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September 14, 2010

Donald Berwick, MD
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Room 445–G,
Hubert H. Humphrey Building, 200
Independence Avenue, SW.,
Washington, DC 20201

RE: CMS–1510-P
Medicare Program; Home Health Prospective Payment Rate Update for
Calendar Year 2011; Changes in Certification Requirements for Home
Health Agencies and Hospices

Dear Dr. Berwick:

The National Association for Home Care & Hospice (NAHC) is the largest trade association in the country representing home health agencies. NAHC members represent the entire spectrum of home health agencies, including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and freestanding, proprietary home health agencies. NAHC members serve nearly 3 million Medicare home health beneficiaries each year.

We are writing to request your consideration of our comments, submitted on behalf of these agencies, on “Medicare Program: Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes to Certification Requirements for Home Health Agencies and Hospices” (CMS-1560-P).

NAHC recognizes the challenges faced by the Centers for Medicare & Medicaid Services (CMS) in its responsibilities to carry out the mandates of the Affordable Care Act of 2010 while also managing its pre-existing obligations under Medicare law. NAHC also agrees that it is essential that CMS protect Medicare beneficiaries from improper and

abusive Medicare spending and the inappropriate practices on the part of a few home health agencies. However, CMS must also recognize that its best intentions are insufficient when devising policy proposals if those proposals serve to weaken or eliminate access to high quality, compliant home health services. The policies must address system weaknesses and deficits, but not at the expense of bona fide Medicare home health patients. Likewise, CMS needs to recognize that its policies can have a negative effect on the home health services delivery system by putting compliant home health agencies at high risk of closure due to improper rate reductions and overreaching regulatory safeguards intended to impact only the noncompliant or abusive providers.

NAHC has had a long and successful history of working with CMS to devise policies that do more good than harm. We are committed to continuing that role. In that spirit, we offer the following comments on the proposed rule.

Table of Contents

I. OVERALL COMMENTS..... 5

 A. Impact Analysis..... 5

 B. Cost Increases..... 6

II. PROPOSED CASE MIX WEIGHT ADJUSTMENTS 6

 A. Summary 6

 B. Specific Comments on Case Mix Creep Adjustments 8

III. FACE-TO-FACE PHYSICIAN ENCOUNTER REQUIREMENTS..... 21

 A. Summary 21

 B. Risk of Harm 22

 C. Certification Timing..... 23

 D. Encounter related to reason for home health and documentation requirements 24

 E. Face-to-Face Encounter by Telehealth..... 26

 F. Physician and Non-physician Practitioner Employee Status..... 27

 G. Physician Signature and Date 28

IV. Proposed Therapy Service Requirements..... 28

 A. Summary 28

 B. Risk of Harm 29

 C. Reassessment on the 13th and 19th Visit..... 30

 D. Non-coverage of Transient, Easily Reversible Conditions..... 31

 E. Maintenance Therapy 32

 F. Other Therapy Considerations and Recommendations 34

V. 36-MONTH RULE LIMITS on TRANSFERS of PROVIDER ENROLLMENT and BILLING PRIVILEGES..... 34

 A. Summary 34

 B. The Problem Must Be Defined..... 37

 C. The Solution Does Not Fit the Problem..... 38

 D. Other Available Policy Tools May Provide Better Results 39

 E. The Rule and Proposed Revisions Contain Internal Inconsistencies on Application to Ownership Changes Following Previous Ownership Changes 39

 F. To the Extent That the 36 Month Rule is Retained It Should Only Apply to 100% Direct Ownership Changes 40

 G. Exceptions Should Be Modified to Include Low-Risk Transactions..... 41

 H. The Rule Should Apply Prospectively Only..... 43

 I. Conclusion..... 44

VI. HH CAHPS.....	44
A. Summary	44
B. Risk of Harm	44
VII. WAGE INDEX	45
VIII. NEW PROVIDER CAPITALIZATION	46
IX. MISCELLANEOUS TOPICS	47
A. Hypertension Diagnosis Coding Under the HHPPS	47
B. Collecting Additional Claims Data for Future HHPPS.....	48
C. Solicitation of Comments: Future Plans to Group HHPPS Claims Centrally During Claims Processing.....	49
IX. HOSPICE FACE-TO-FACE ENCOUNTER.....	50
A. Summary	50
B. Insufficient Hospice Physician/NP Staffing to Meet the Requirement.....	50
C. Prohibitive Costs of the Hospice Face-to-face Encounter Requirement.....	51
D. Inadequate CMS Resources to Ensure Accuracy of Previous Hospice Service.	51
E. Challenges Related to Meeting Face-to-face Requirement for Patients Readmitted While Actively Dying	52
F. Application of Benefit Period Standard for Patients with Sequential Hospice Care/Terminal Diagnoses.....	52
G. Potential for Professional/Ethical Conflict	53
X. CONCLUSION.....	53

I. OVERALL COMMENTS

A. Impact Analysis

CMS perpetuates its useless approach to analyzing the impact of the proposed rule by simply quantifying the percentage cut in rates on a geographic basis. Further, the NPRM impact analysis offers little substantive understanding of the cost impact of such proposed rules as the physician face-to-face encounter requirement, revisions to therapy assessment, coverage and documentation standards, coding change proposals, and CAHPS compliance. The estimated costs are vastly understated because they do not include the sizeable administrative expenses that home health agencies will incur to implement any of the changes beyond the cost of some of the form revisions.

A valid and useful impact analysis starts with an understanding of the results of the combination of rate cuts and cost increases that the NPRM will bring to home health agencies. Once such is fairly and accurately determined, the impact analysis must begin with the highest of priority concerns—impact on access to care—as that is the central purpose of Medicare. Second, the impact analysis should continue with an evaluation of the effect of the NPRM on Medicare spending in a whole sense, not just the effect on home health services spending. For example, if the analysis of the NPRM’s impact on access to care shows that thousands of Medicare beneficiaries will no longer have home health care available or that it will be significantly delayed, Medicare spending will rise as a result of a shift to higher cost care such as skilled nursing facility services or extended inpatient stays.

The impact analysis should also evaluate the impact of the NPRM on another stakeholder—home health agencies as businesses. Such evaluation should start with the ongoing viability of the individual businesses and the industry as a whole. Among the many elements that should be reviewed is whether the business will be paid less than the cost of the delivery of care. Another element is the workforce impact—will health care workers take their talents to other care sectors because of reductions in compensation and benefits. Access to capital is also an important factor to evaluate. If the proposed rule changes restrict access to capital, there may be reduced use of efficiency-related technologies or business expansions to achieve economies of scale. Lack of access to capital could also mean an inability to meet ongoing payroll obligations because of cash flow problems.

One other flaw in the CMS impact analysis is its limited review to a single year. This is particularly concerning when the proposed rule extends rate cuts into a second year. An impact analysis that does not evaluate the impact of cuts in payment rates for both of the years proposed is completely invalid and in violation of CMS obligations under the Regulatory Flexibility Act.

These are only a few of the significant weaknesses in the CMS impact analysis. NAHC strongly recommends that CMS conduct a thorough and valid impact analysis, consistent

with the concerns referenced above. Further NAHC recommends that the impact analysis be performed and published before the Final Rule is issued.

B. Cost Increases

As discussed above, the series of proposals in the NPRM will significantly increase the cost of providing home health services. However, not only has CMS failed to fully display those cost increases, CMS proposes rate reductions while increasing care costs.

The Market Basket Index, as constructed by CMS, fails to include consideration of the direct cost increases that CMS rules may have on the delivery of care. Instead, it evaluates general cost changes such as the cost of caregivers, transportation, insurance, and office space. This approach does not provide CMS with the information needed to adjust payment rates in relation to regulatory cost increases.

Where the home health services “product” changes because of new regulatory, administrative requirements, CMS must include an element in the Market Basket Index to address the resulting cost changes. Alternatively, CMS must adjust base payment rates to account for such cost as it has done in the past (albeit later than it should have) for costs such as OASIS.

II. PROPOSED CASE MIX WEIGHT ADJUSTMENTS

A. Summary

The Medicare program provides payment for home health services under a model known as the Home Health Prospective Payment System (HH PPS). A prospective payment model replaced a per visit, cost reimbursement model in October 2000, consistent with the mandate under the Balanced Budget Act of 1997.

From 2000-2007, the Centers for Medicare and Medicaid Services (CMS) devised HH PPS to provide a 60-day episodic payment based on one of 80 patient case-mix categories. The patient specific category was determined based upon a scoring system that led to the assignment of a case-mix weight that was applied to the base episodic rate to calculate the payment.

Beginning in 2008, CMS instituted a new 153 category model, revising the scoring system to assign the case mix weights. That same year, CMS initiated a series of adjustments to the base episodic payment rate known as the Case Mix Weight Change Adjustment. This adjustment was intended to reduce payment rates to take into account increases in case mix weights (and resulting payment levels) that was not due to changes in the condition of patients. Case mix weight changes related to improved coding accuracy, coding behavioral changes, and increased utilization of therapy services in contrast to patient condition changes are the basis of the adjustment.

CMS has implemented three case mix weight change adjustments to date—2.75% rate reductions in each of 2008, 2009, and 2010. It planned on an additional reduction of 2.71% in 2011. In its recent Proposed Rule, CMS proposes to increase the 2011 adjustment to 3.79% and to add a further 3.79% adjustment in 2012.

The case mix weight change analysis performed by CMS fails to consider numerous factors highly relevant to a determination as to whether the increase in average case mix weights is related to changes in patient characteristics. The flaws include reliance on hospital DRG data whereas over half of all Medicare home health patients are admitted to care from a setting other than a hospital and many of the patients receive care far extended past an initial episode. In addition, relevant data demonstrates that home health care patients have increased functional limitations and more complex clinical conditions than in past years. Also, much of the increase in case mix weights is due to home health agencies complying with Medicare instructions regarding patient coding consistent with the 2008 version of HH PPS, coding weight changes that accurately reflect the changed condition of Medicare patients. Overall, payment rate reductions due to case mix weight changes are not warranted because Medicare expenditures for home health services are well within budgeted levels, thereby demonstrating that aggregate spending has not increased such as to permit CMS to exercise its authority to adjust payment rates.

Recommendations:

1. Rescind its proposed payment rate cuts related to the alleged “nominal” increase in average case mix weights for the reasons set out in detail below and withhold adjustments until a reliable model for assessing case mix weight changes can be developed and tested.
2. Develop an accurate and reliable model to evaluate changes in case mix weights consistent with the whole nature of patients served in home health care, not just those discharged directly to home health from hospitals. This model must:
 - Recognize that home health patients are often treated in the home for conditions other than the primary condition that led to hospitalization.
 - Consider that patients may have multiple episodes of care such that a prior hospitalization is of little relevance to the condition of the patient.
 - Consider that there are changes in clinical practice that may increase case mix weights while actually decreasing total patient costs to Medicare, an outcome that should not be discouraged by reducing payment rates.
 - Take into account that many changes in case mix weights occur concurrently with increased care costs for the provider, e.g. increased therapy visits, and that a rate reduction in such circumstances is illogical.
 - Ultimately meet a minimum requirement for a level of accuracy and reliability that is at least equivalent to the case mix adjustment model that it is assessing. The current HH PPS case mix model reportedly originally had an R-squared explanatory power of over 40% while the case mix weight change assessment model falls far short of that benchmark at around 10%.

3. Alternatively, CMS must recalculate the estimated nominal case mix weight change to take into account the appropriate use of hypertension as a diagnostic coding and the separate impact of any case mix weight changes on the distinct case mix adjuster for medical supplies. To the extent that CMS maintains its proposal to drop hypertension coding from the HH PPS case mix weight scoring, CMS must limit the impact of the case mix weight adjustment to the length of time that the hypertension coding was in use in its coding weight analysis (2008 only) and to restore the base rates to the appropriate level after that point.
4. Further, there should be no application of the adjustment to medical supplies unless CMS can establish that there is a change in case mix weights specifically regarding medical supplies that is not due to real changes in patient characteristics.
5. Limit any single year rate reductions reflecting any statutory rate reductions and/or case mix weight change adjustments to no greater than a combined 2.5%.

B. Specific Comments on Case Mix Creep Adjustments

CMS has proposed a coding weight change adjustment of 3.79% in 2011 and 2012. This adjustment allegedly reflects “nominal” changes in case mix weights that are not related to changes in patient characteristics in 2000-2008 not already implemented by CMS. Currently, CMS had scheduled a 2.71% adjustment in 2011 intending to reflect nominal coding weight changes through 2005.

These regulatory cuts are on top of a series of rate cuts stemming from the Affordable Care Act. Under the health care reform legislation, an estimated \$39.7 billion in Medicare spending on home health services will be lost between 2011 and 2019. These cuts include: a 1 point reduction in the annual inflation update (Market basket index); a \$7 billion reduction in outlier payments; the institution of an annual productivity adjustment to the inflation update beginning in 2015; and a 4 year phase-in of rate rebasing starting in 2014.

If these cuts are implemented, NAHC estimates that by 2012 nearly 50% of all home health agencies will be paid less than the cost of care to Medicare patients. While a typical case mix weight change adjustment in other provider sectors may bring a reduction in profit margins only, in home health the adjustment occurs where the higher payments from increased case mix weights are offset by increased costs.

On a state-by-state basis, the cost report data shows a dire situation after the proposed rate cuts, indicating that access to care will be significantly lost.

Percentage of Home Health Agencies with Projected Margins of 0 or Less, by State		
Potential Risks from a Combination of a CMS Regulatory Payment Cut of 3.79% in 2011 and 2012 along with Scheduled Rate Cuts under the Patient Protection and Affordable Care Act (P.L. 111-148)		
	2011	2012
NATIONAL	41.2%	49.6%
Alabama	40.5%	53.6%
Alaska	84.6%	84.6%
Arizona	41.4%	51.7%
Arkansas	48.9%	56.7%
California	53.4%	63.2%
Colorado	38.5%	43.1%
Connecticut	23.2%	27.5%
Delaware	42.9%	42.9%
District of Columbia	36.4%	40.9%
Florida	29.7%	39.1%
Georgia	44.7%	51.3%
Hawaii	75.0%	87.5%
Idaho	64.1%	71.8%
Illinois	36.8%	45.9%
Indiana	40.7%	49.3%
Iowa	47.1%	52.2%
Kansas	47.5%	51.7%
Kentucky	37.5%	44.3%
Louisiana	28.4%	34.6%
Maine	55.6%	66.7%
Maryland	34.2%	53.7%
Massachusetts	31.4%	38.1%
Michigan	40.3%	49.7%
Minnesota	47.4%	52.6%
Mississippi	25.6%	35.9%
Missouri	51.3%	59.0%
Montana	59.4%	65.6%
Nebraska	59.7%	61.4%
Nevada	50.0%	56.5%
New Hampshire	22.6%	38.7%
New Jersey	51.4%	57.1%
New Mexico	40.0%	46.7%
New York	64.0%	74.4%

North Carolina	29.1%	36.7%
North Dakota	73.7%	73.7%
Ohio	30.3%	33.8%
Oklahoma	47.2%	59.0%
Oregon	81.4%	88.4%
Pennsylvania	31.8%	39.9%
Puerto Rico	69.2%	76.9%
Rhode Island	17.7%	29.4%
South Carolina	47.6%	52.4%
South Dakota	55.9%	61.8%
Tennessee	30.7%	36.8%
Texas	43.7%	54.1%
Utah	29.9%	40.3%
Vermont	33.3%	41.7%
Virginia	43.9%	50.3%
Washington	45.5%	50.0%
West Virginia	50.0%	64.6%
Wisconsin	60.0%	67.1%
Wyoming	63.6%	72.7%

As this chart notes, there are nearly 50% of all home health agencies with Medicare margins below zero after the proposed rate cuts. In fact, six states and the Commonwealth of Puerto Rico have more than 70% of providers with below zero margins after the proposed cuts with Oregon at 88.4%. (Alaska 84.6%;Hawaii 87.5%; Idaho 71.8%; New York 74.4%; Oregon 88.4%; Puerto Rico 76.9%; and North Dakota 73.7%)

NAHC recognizes that the adjustments address several factors that lead to increases in average case mix weights including abusive claims coding practices, improved accuracy in coding, and increases in therapy services that result in higher coding weights. The proposed 3.79% adjustments in 2011 and 2012 appear to be based primarily on the proper inclusion of hypertension as a patient diagnosis and modified provision of therapy services consistent with the HH PPS model revision in 2008.

With HH PPS, the coding weight is significantly affected by the volume of therapy services. From 2000-2007, increased coding weight occurred when the patient received 10 or more therapy visits in a 60 day episode. Beginning in 2008, coding weight adjustments occur with 6, 14, and 20 visits in the episode.

When CMS applies rate reductions related to coding weight increases due to therapy, it reduces payment while the provider incurs greater care costs. With abusive “upcoding” a provider would get higher payments without higher costs. In this context, CMS errs in equating all increases in therapy services as “nominal” case mix change rather than changes in patient characteristics. A rate adjustment that reduces payment levels when a provider experiences cost increases is not a logical application of the limited authority

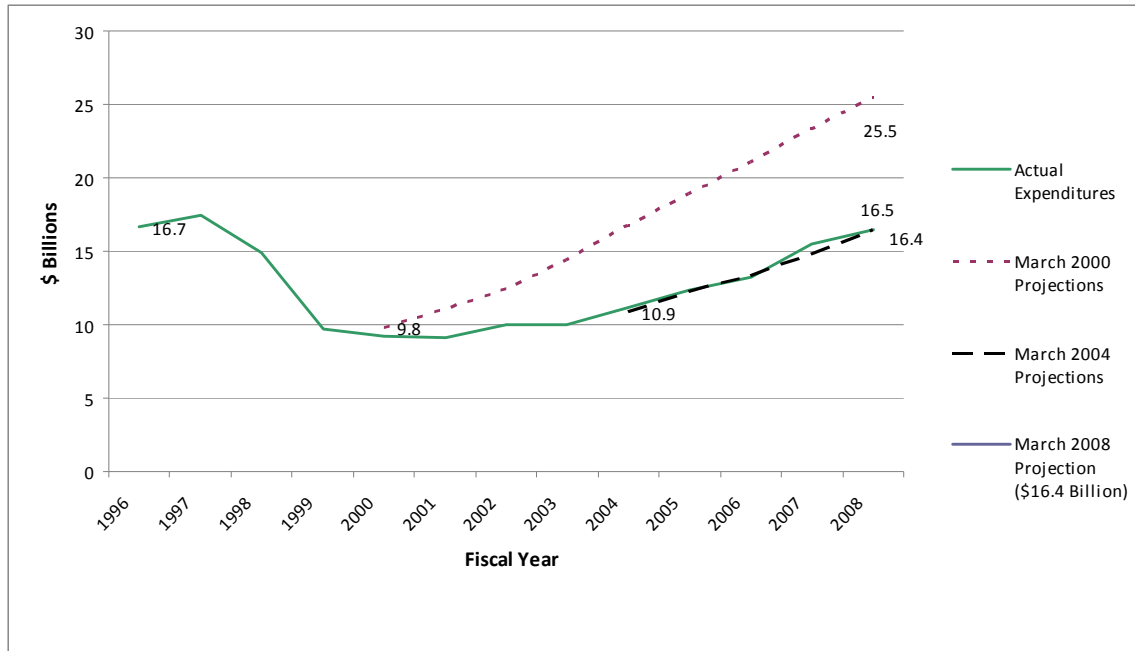
that CMS has under 42 USC 1395fff to adjust payment rates when care mix weight changes that do not reflect patient characteristic changes occur.

Therapy Utilization

	6 to 9 visits	10 to 13 visits	14 or more visits
2002	9% of episodes	11% of episodes	12% of episodes
2007	9% of episodes	15% of episodes	12% of episodes
2008	12% of episodes	11% of episodes	15% of episodes

Therapy services for home health patients have increased in volume since the start of HH PPS in 2000. At the same time, patient outcomes have improved and Medicare spending per patient and in the aggregate overall has stayed well below projections by the Congressional Budget Office (CBO).

CBO Baselines and Actual Spending, FY 1996 - FY 2008 (in billions)													
	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Actual Expenditures	16.7	17.5	14.9	9.7	9.2	9.1	10.0	10.0	11.2	12.4	13.2	15.5	16.5
March 2000 Projections					9.8	11.1	12.5	14.4	16.8	18.9	21.1	23.3	25.5
March 2004 Projections									10.9	12.3	13.3	14.8	16.5
March 2008 Projection (\$16.4 Billion)													16.4



Under 42 USC 1395fff(b)(3)(B)(iv), CMS may make adjustments to the base prospective payment rate only if there is a “change in aggregate payments...during the fiscal year or years that are a result of changes in coding or classification of different units of services that do not reflect real changes in case mix...” In home health services, Medicare expenditures have been equal to or lower than projections and estimates by CBO since the beginning of HH PPS. For example, CBO projected \$16.5 billion in spending in 2008 and spending equaled \$16.5 billion in 2008. As such there is no increase in aggregate expenditures that warrants the application of the statutory authority under 42 USC 1395fff(b)(3)(B)(iv).

The nightmare presented regarding continued access to home health services in the face of well controlled Medicare spending on home health services is a creature of a fatally flawed model for evaluating real changes in patient characteristics. The evidence definitively shows that patients admitted to home health services are sicker and in need of greater care resources. Yet, the evaluation model used by CMS shows virtually no change in patients in nearly a decade.

There is strong evidence that the nature and severity of the patients receiving home health services has changed since 2000. Those changes are due to a number of factors including reimbursement system changes in other provider sectors that lead to reduced inpatient stays and more restrictive admission requirements in other settings. In addition, there has been a nationwide rebalancing of care in favor of community care settings leading to a higher condition severity in home care admissions. However, the CMS assessment method relies significantly on the DRG patient classification system which does not adequately account for the discharge condition of the patient as it relates to home care

needs. Finally, more than one half of home health care patients are admitted from a setting other than an inpatient hospital.

Two independent studies confirm that the patients admitted to home health care are more acutely in need of more intensive care than ever. Further, these studies confirm that the CMS methodology for evaluating case mix weight changes is significantly flawed and unreliable.

Dobson/DaVanzo, a Washington, DC-based economic analysis firm, concludes that the case mix weight change assessment model used by CMS is “unreliable” and that there is important evidence of changes in patient characteristics that are not considered by that model. *Analysis of Home Health Prospective Payment System Notice of Proposed Rulemaking for Calendar Year 2011*, Dobson/DaVanzo (September 13, 2010). (Attached as Exhibit A) (hereinafter “*Report*”) The report cites seven separate technical concerns with the CMS assessment model that could lead to an underestimation of the “real” case mix change.

1. The evaluation model is unreliable. *Report* pp 6-7
 - “The model contains numerous input variables that are not statistically significant and may provide spurious results.”
 - 848 of the 902 variables are APR-DRG related to prior use hospitalization
 - 40% of the top 25 variables are different from one model to the next
 - The explanatory power of the models falls 46% between the 2000-2007 model and the 2007-2008 model
2. Numerous model explanatory factors are neither statistically significant nor relevant *Report* pp 7-10
 - 94% of the variables are APR-DRG related designations of prior acute care hospitalizations
 - The variables only explain 0.6% of case mix change
 - The variables are not related to patient acuity
 - Only 39% of home health patients come directly from a hospital
3. APR-DRG variables are less and less relevant for multiple episode patients *Report* p. 10
 - 38% of HH PPS episodes are recertifications (2nd, 3rd, or later episodes)
4. Therapy use changes cannot be explained in the model *Report* pp 10
 - CMS admits it cannot explain the correct amount of therapy expected for patients and uses therapy volume as a proxy for volume
 - The variables in the CMS model admittedly cannot explain changes in therapy use
 - 38% of the case mix weight change is therapy related, which cannot be explained and is unaddressed in the model
 - CMS should use alternative variables predictive of therapy use as recommended by MedPAC or individual claim review

5. The model forecasts less real case mix change as acute care hospital stays decrease *Report* p. 10-11
 - “quicker and sicker” hospital discharges would lead to sicker patients admitted to home health care
 - Patients may be diverted to home care from Inpatient Rehabilitation Facilities due to the CMS 60% rule and SNFs
 - Technology increases and policy incentives favor the home setting over institutional care
6. Patient care capabilities are changing in home health services *Report* p. 11
 - Diagnostic-specific care protocols allow targeting of patient populations
 - Trend supports notion that HHA patients are of higher acuity as care is targeted to more severely ill patients
7. The model is based on administrative data rather than clinical data *Report* p.11-12
 - No home health clinical data is used in the model
 - Model does not capture information on changes in patient selection by providers

A second and independent study was performed by another Washington DC-based think tank, Lewin Group. Lewin reached comparable conclusions regarding the reliability of the CMS model in its critique. It offers six significant reasons why the model is unreliable. *Evaluation of the Proposed Coding Adjustment for Home Health Prospective Payment System for CY 2011*, The Lewin Group (September 14, 2010). (Attached as Exhibit B) (hereinafter “*Evaluation*”)

1. The model relies on the APR-DRGs while only 39% of home health patients are admitted from a hospital stay. *Evaluation* p. 5
 - “...somewhat disingenuous since the APR-DRG and APR-DRG risk of mortality were relevant for a small portion of the home health episodes...”
2. No explanation provided on segmented choice of periods of evaluation. *Evaluation* p. 5
 - “...unclear why Abt subdivided the 2000-08 period in 2007
 - Case mix in 2008 should have the same regardless of the change in HH PPS
 - “...to minimize the possibility for shifts in the relationship between resource requirements and explanatory variables, Abt could have subdivided the 8-year period in half or at least performed some sensitivity analysis to choose the time periods.”
3. Drop in Inpatient length of stay. *Evaluation* pp. 6-7
 - While Abt included variables related to inpatient stays, “the estimated coefficients are not consistent with these expectations” that “the

coefficient for any stay would be positive and the coefficient for the number of days would be negative.”

- The coefficient is the opposite of expectations: it was -0.8141 for any hospital stay and 0.00782 for the number of days
- “...the Abt report does not discuss what signs are consistent with known relationships, and hence, it is not in a position to judge the signs of the coefficients.”

4. Problems with multicollinearity. Evaluation p. 7

- Abt does not perform any multicollinearity diagnostic statistics or consider the remedy of combining some of the variables
- The model uses a large number of variables that do not have much variation
- “The lack of variation in the values of the dependent variables and the close interaction among them is likely to pose problems with the prediction of the dependent variables.”

5. Difference in R-square. Evaluation p. 7

- The regression model R-square dropped from 19% to 10% in the 2008 analysis
- The R-square of the 80 HHRG model was at 0.21-- much lower than the R-square for the 153 HHRG model at 0.44
- This suggests that the regression model analysis for 2008 should have had a higher R-square
- The decrease in the R-square is “unclear and unexplored.”

6. CMS uses inconsistent approaches in estimating the coding adjustment among provider sectors. Evaluation p. 7

- Over the last four years, CMS has used different case mix change assessment models for post-acute providers: IRFs, LTCHs, and HHAs.

In summary, based on these two independent analyses and NAHC’s own review, the unreliability of the case mix weight change assessment model is due to the following:

1. It cannot explain changes in the use of therapy services. The factors considered in the CMS model do not have adequate relationship to therapy utilization and CMS had previously rejected these factors when originally designing HH PPS.
2. It relies too heavily on hospital discharge data when more than half of all patients (61%) are admitted to home health from settings other than a hospital. Further, the APR-DRGs are not related to home care acuity given that they focus on the primary purpose of the patient’s hospitalization rather than the post-discharge condition and needs of the home health patient. Also, the DRGs have little or no relevance to a home health patient’s condition in the second and later episodes of care, a growing category of patient utilization.

3. The model relies too heavily on assumptions and beliefs rather than empirical evidence
4. To the extent that the inpatient DRG is relevant, data shows that average case mix weight for inpatient services provided to patients discharged to home health services increased in 2008, thereby demonstrating that the acuity level of the home health patient has changed.
5. The explanatory power of the model in comparison to the HH PPS itself is 46% lower, falling from 19% to 10%.
6. It fails to integrate changes in care delivery and payment methodologies in other provider sectors such as hospitals, nursing facilities, long term care hospitals and rehabilitation hospitals that affect the nature of patients in home health services. Skilled nursing facility and inpatient days in an acute care hospital have been reduced by changes in clinical practice and the influence of reimbursement system changes. This leads to higher acuity in those patients discharged to home health care from those settings.
7. It fails to account for home health coding policy changes that negate the risk of coding weight increases, such as the proposed elimination of hypertension from the coding model, while CMS proposes a permanent rate reduction related to the impact of hypertension coding. When the case mix adjustment model is revised as proposed by CMS, all of the case mix categories need to be re-weighted and rebalanced to achieve budget neutrality.
8. The model fails to account for any changes in home health agency behavior related to patient populations served. These would include a marketing effort targeted to increasing the proportion of high therapy utilization type patients.
9. The proposed rule applies the case mix weight change adjustment to Non-Routine Medical Supplies (NRS) without any analysis of changes in medical supply utilization, need, or changes in patient characteristics of supply users. In addition, the CMS model never evaluated any changes in case mix weights in 2008 for the separate NRS case mix adjustment model. The evaluation of HHRG changes cannot substitute for an appropriate NRS case mix change evaluation.
10. It does not consider that certain coding adjustments, e.g. therapy utilization, accompany an increase in provider costs rather than reimbursement alone. Such consideration warrants recognition relative to the validity of any rate reduction and the impact on access to care.
11. It penalizes providers for improved accuracy in patient assessment and coding. The natural and foreseeable consequence is that such improvements are discouraged.

With respect to the concerns expressed regarding the proposed actions relative to the application of hypertension diagnostic codes, several additional points are worthy of mention.

First, it appears that the CMS case mix weight change analysis never specifically evaluated any evidentiary basis for its determination that the hypertension diagnostic coding is a nominal change in case mix. Instead, all that CMS offers is its assumption that the increased coding of hypertension is nothing more than increased coding of hypertension.

Second, the 2008 HH PPS methodology is based upon a determination that a hypertension diagnosis indicates a higher degree of resource need and utilization by patients with that diagnosis. Nothing in the CMS analysis indicates that anything other than this original finding is supportable. As such, concluding that an increase in patients with a hypertension diagnosis is anything other than a change in patient characteristics is illogical and in error.

Third, CMS opines that the 2003 changes in diagnostic coding guidance led to the increase in incidence of hypertension coding rather than changes in patient characteristics. However, the 2003 changes were fully operational at the time in 2007 when CMS proposed and finalized the 2008 HH PPS version that includes hypertension as a factor in the patient classification system.

Fourth, with CMS's proposal to eliminate hypertension from the HH PPS classification model, it is wholly inconsistent to institute a permanent rate reduction that is based on one single year of the application of hypertension as a diagnostic factor in case mix weight calculation. The impact from the application of that factor in 2008 is eliminated starting in 2011. To maintain a rate reduction beyond the one year that was evaluated results in an endless annual recovery of any alleged overpricing of services. For example, if the hypertension factor resulted in \$100 million in allegedly excess payments in 2008, it is logically wrong to reduce future payments by \$100 million every year thereafter given that the source element for the overpricing is eliminated.

Fifth, when the 2008 HH PPS case mix weights were devised, it was necessary for CMS to apply a budget neutrality adjustment to the abstract weights in order to prevent an aggregate payment reduction for home health services. The 2007 Final rule includes an approximate 14% adjustment to achieve budget neutrality. That adjustment is based upon the inclusion of hypertension in the HHRG calculation. Reform of the HHRG scoring model by eliminating the hypertension element requires CMS to rebalance all the HHRG weights to maintain budget neutrality.

The Dobson/DaVanzo *Report* confirms these concerns with the manner in which CMS considered changes in the volume of patients coded with hypertension and the resulting impact on the case mix change adjustment.

“Eliminating the two hypertension codes from the case-mix calculation decreases home health PPS payments by 1.78 percent, according to an OCS analysis. This change would affect the 2008 HHRG case-mix grouper as applied in 2011. This, in effect, again takes out the hypertension effect on home health PPS a second time..

To account for these types of effects, whenever CMS produces a new grouper, it always implements a budget neutrality adjustment to ensure that the new grouper payments are equal to overall payments from the prior year’s grouper. CMS does not propose to do this for the 153 HHRG grouper for 2011 after the hypertension codes are removed. Hence, the reduction in 2011 payments is not 4.75% as indicated in the NPRM, but rather 6.53% (4.75% + 1.78%) because CMS does not factor in the payment results of the elimination of the hypertension codes. In order to correct the payment reduction to the 2011 projected payment reduction to the estimated 4.75%, CMS will need to increase the HHRG grouper case weights by 1.78%. Otherwise CMS is taking back the hypertension effect twice: one in the pair of 3.78% payment reductions, which includes hypertension coding, and yet again in a revised grouper.” *Report* pp. 15-16

The *Report* and *Evaluation* also provide important insights into the changing characteristics of home health patients that is not accounted for in the CMS review of case mix weight changes from 2006 through 2008.

The Dobson/DaVanzo *Report* offers three external data references that are clear indications of real changes in patient characteristics.

1. Medicare Expenditure Panel Survey (MEPS) Data Analysis, *Report* p.12
 - Data shows patients getting sicker every year
 - 15% “real” case mix change between 2000-2007
2. OCS data analysis on OASIS measures regarding a patient’s functional status unrelated to HH PPS HHRG calculations, *Report* pp. 12-14
 - A one size fits all approach to the adjustment will have a disproportionate effect on some regions because of the wide ranging variations in case mix weights and case mix weight changes
 - OASIS data shows increased patient acuity from 2006-2008 as measured by ADL assessments of decreasing functional capabilities of home health patients
 - Declines in all nine functional categories
3. OCS data analysis on OASIS measures of clinical conditions that are unrelated to HH PPS HHRG calculations, *Report* pp.14-15
 - OASIS data shows a “large increase” in acuity as measured by changes in clinical conditions

- Increases in the number of patients requiring IV therapy, parenteral nutrition and those that have urinary tract infections at the start of care
- Increased inability to manage oral and injectable medications

The OASIS measures used in these analyses are not likely to be “upcoded” to secure higher reimbursement as none of these measures has a direct or indirect impact on the level of payment under HH PPS. Further, the decrease in functional capabilities can be easily correlated with increase in the use of therapy services as both physical and occupational therapists directly address the ADL incapacities that are the focus of these OASIS findings.

The Lewin Group’s *Evaluation* mirrors the Dobson/DaVanzo’s *Report* in finding that “non-case mix related OASIS items, such as grooming and light meal preparation have shown increasing functional limitations among home health patients.” *Evaluation* at 8.

Lewin also notes a crucial external data finding that demonstrates that home health patients are admitted from hospital stays with a higher degree of acuity in their condition.

“The acute care (inpatient prospective payment system (IPPS)) CMI for cases discharged to home health agencies reflects the patient severity of the patients discharged to home health agencies. As one of the measures for patient severity is prior hospitalization, it is believed to be unaffected by the home health CMI. The CMI for the prior hospitalization can be assumed to be a proxy measure of the “real” case mix index. Based on our analyses of the 2007 and 2008 MedPAR data (Medicare discharges from short term acute care hospitals, we found that the CMI (MS DRG-based CMI) of cases discharged to home health agencies increased by 2.5 percent from 1.588 in 2007 to 1.63 in 2008.

Furthermore, we also found that among the acute care cases discharged to home health agencies, the proportion of cases categorized as Medicare Severity Adjusted Diagnosis Related Groups (MS DRGs) with complications and comorbidities increased by 3 percentage points from 25 percent in 2007 to 28 percent in 2008. This implies that the real case mix index due to comorbidities most likely increased for the cases discharged to home health agencies.

Given that Medicare pays short term acute care hospitals based on MS DRGs, it may be a more reliable and independent method to measure changes in case mix index compared to APR DRG. At least 2.5 percent of the change in case mix index for home health episodes can be attributed to change in patient acuity compared to the 1.76 percent based on Abt’s regression.” *Evaluation* at 8

In summary, the CMS/Abt model for assessing the reasons and explanations for changes in case mix weights in HH PPS is unreliable. Further, there is objective evidence that patients admitted to home health services have an increased acuity level and a greater need for rehabilitative therapy services. On the other hand, the CMS/Abt assessment uses data sources that do not portray the conditions of home health patients upon admission to home health care. In fact, the model does not portray the clinical condition of the vast majority of home health patients at all.

The CMS proposed rate reduction also is in conflict with the trend in spending for home health services. Medicare expenditures are fully in line with budget expectations thereby rendering illogical the application of rate reduction authority that is available only when expenditures have improperly increased due to coding behavior.

Recommendations:

1. Rescind its proposed payment rate cuts related to the alleged “nominal” increase in average case mix weights for the reasons set out in detail below and withhold adjustments until a reliable model for assessing case mix weight changes can be developed and tested.
2. Develop an accurate and reliable model to evaluate changes in case mix weights consistent with the whole nature of patients served in home health care, not just those discharged directly to home health from hospitals. This model must:
 - Recognize that home health patients are often treated in the home for conditions other than the primary condition that led to hospitalization.
 - Consider that patients may have multiple episodes of care such that a prior hospitalization is of little relevance to the condition of the patient.
 - Consider that there are changes in clinical practice that may increase case mix weights while actually decreasing total patient costs to Medicare, an outcome that should not be discouraged by reducing payment rates.
 - Take into account that many changes in case mix weights occur concurrently with increased care costs for the provider, e.g. increased therapy visits, and that a rate reduction in such circumstances is illogical.
 - Ultimately meet a minimum requirement for a level of accuracy and reliability that is at least equivalent to the case mix adjustment model that it is assessing. The current HH PPS case mix model reportedly originally had an R-squared explanatory power of over 40%, while the case mix weight change assessment model falls far short of that benchmark at around 10%.
3. Alternatively, CMS must recalculate the estimated nominal case mix weight change to take into account the appropriate use of hypertension as a diagnostic coding and the separate impact of any case mix weight changes on the distinct case mix adjuster for medical supplies To the extent that CMS maintains its proposal to drop hypertension coding from the HH PPS case mix weight scoring, CMS must limit the impact of the case mix weight adjustment to the length of

time that the hypertension coding was in use in its coding weight analysis (2008 only) and to restore the base rates to the appropriate level after that point. Further, there should be no application of the adjustment to medical supplies unless CMS can establish that there is a change in case mix weights specifically regarding medical supplies that is not due to real changes in patient characteristics.

4. Limit any single year rate reductions reflecting statutory rate reductions and/or case mix weight change adjustments to no greater than a combined 2.5%.

III. FACE-TO-FACE PHYSICIAN ENCOUNTER REQUIREMENTS

A. Summary

The Centers for Medicare & Medicaid Services (CMS) published its proposal for implementing Section 6407 of the Affordable Care Act that requires home health patients to have a physician face-to-face encounter prior to the physician's certification of the need for home health services. Section 6407 requires that: prior to certification, the physician (or certain non-physician practitioners) must document that he or she had a face-to-face encounter with the patient within a reasonable timeframe as determined by the Secretary. The statutory language references certification only, and does not refer to recertification. The statute allows for the encounter to occur within 6 months prior to certification.

CMS's proposed revision to 42 CFR §424.22 identifies much narrower timeframes and proposes additional requirements and limitations not required by the statute. NAHC is concerned about the proposals for expanded requirements regarding:

1. Certification timing
2. Documentation requirements and the requirement that the encounter explicitly be tied to the home health care services
3. Standards for allowing face-to-face encounter by telehealth
4. Restrictions on non-physician practitioner employment status
5. Physician signature and dating requirements

NAHC expresses recognition that CMS is limiting the face-to-face encounter requirements to initial certifications in accord with statutory language. Nevertheless, NAHC strongly recommends that CMS postpone implementation of the physician face-to-face encounter requirements until CMS and other stakeholders can determine that the policy implementation will not negatively impact access to care, that physicians are informed and educated regarding their responsibilities, that Medicare beneficiaries are fully informed of their obligations, and that the necessary certification statements and documentation forms are developed, tested, and determined appropriate. With previous

experiences involving certifying physicians, it can be fairly estimated that physicians will not be prepared for these new responsibilities by the proposed effective date of January 1, 2011. As such, NAHC recommends that January 1, 2012 be set as the target date for full implementation.

B. Risk of Harm

NAHC cautions CMS on proceeding too quickly to implement the requirements for physician face-to-face encounters for initial certification of need for home health services. Past experiences indicate that physicians can be dissuaded from utilizing necessary home health services for patients because of fear of reprisal or adverse consequences. For example, with the Balanced Budget Act provision that modified the physician certification statement to include a reference to the penalties imposed for fraudulent certification, physicians across the country were temporarily reluctant to work with home health agencies until they fully understood that only the statement had changed. Similarly, with the recent rule requiring a PECOS-enrolled physician as the certifying physician, CMS quickly learned that physicians can misunderstand their Medicare administrative responsibilities as it was uncovered that the physicians had confused the deadline for PECOS enrollment needed for physician services payment from the earlier deadline for home health certification.

To attempt to determine the level of risk attendant to the proposed face-to-face encounter requirements, a nationwide survey was conducted by Dobson/DaVanzo. In brief, the survey found that the vast majority of home health agencies expect that the proposed requirements would lead to the loss of access to home health care, delays in patient admission to care, and patient refusal of home health care over institutional placement. *Report at 19-20.*

Specifically, the survey found that:

- 85% of respondents expect that physicians would hesitate to refer patient to home health care
- 63% of respondent expect that patients will be referred to other care settings
- 52% report expecting that patients would hesitate to use home health services out of fear that they will not get timely care without traveling to the physician's office
- 47% expect that some patients will opt for institutional care even though they could be safely cared for at home

With respect to specific elements of the proposed requirements:

- 86% of respondent expect that the encounter timing standard will delay referrals and the initiation of care
- 73% expect that the need to connect the encounter directly with the condition treated in home health services would increase the hesitation to refer patients
- 85% view the requirement as making care more timely in other care settings

- 83% believe that the certification documentation proposal will delay the initiation of care

On the crucial point of physician awareness, over 90% of respondents indicated that physicians are not aware of these new requirements, with most of the remaining respondents indicating that they do not know if the physicians are aware.

These survey results clearly demonstrate that Medicare beneficiaries face a significant risk if the policies on face-to-face encounter are not reasonably devised and implanted on after significant physician and community education. What may seem like a simple concept is much more complicated in its application to day to day health care.

C. Certification Timing

CMS proposes that the patient must have a face-to-face encounter with the physician responsible for the home health certification no more than 30 days before, or within 2 weeks of, the start of care. While Section 6407 authorizes the Secretary to establish reasonable timeframes for the physician encounter, the statute specifically permits CMS to establish a 6 month preceding certification timeline. Also, it is our understanding from consultations with Finance Committee staff that the Congressional intent was to establish a time frame for the face to face encounter that extended to the time of the certification of the plan of care.

An extended timeframe for the certifying physician to conduct a face-to-face encounter is essential in the current health care environment where there are growing numbers of hospitalists, hospital-employed emergency rooms physicians, and a severe shortage of primary care physicians in the community. Often patients are under the care of a specialist who will not follow the patient into general patient care in the home setting. As a result, many homebound home health patients could be deprived of necessary home health services if the pre-certification timeframe is too limiting.

NAHC believes that, in many instances, the physician will have sufficient knowledge of the condition for which home health services are ordered if they have seen the patient within the prior 6 months. Patients who have not seen their physician prior to the start of home care would likely have great difficulty meeting the two week post start of care timeframe. This difficulty could arise because of physician unavailability or the inability of the homebound elderly, disabled patient to leave the home to get to the doctor's office. Those patients discharged from inpatient facilities have difficulties securing physician appointments, arranging and paying for special transportation services and availing themselves of working family members within the two weeks as proposed in the rule. Unnecessarily stringent face-to-face requirements that impede access to home health services will result in prolonged hospital stays, increased transfers to post-acute facilities, and increased avoidable re-hospitalizations.

In a recent survey of home health agencies, nearly 90% of all respondents indicate that the proposed time frame will cause access to care problems and delays in starting home

health care services. [More details to be added upon completion of the survey results analysis]. The patient's interests must be considered as paramount in the Secretary's choice of reasonable timeframes for the required encounter.

Recommendations:

- Allow the face-to-face encounter to occur from 6 months prior to initiation of home health services, up to and including the date the physician signs the face-to-face encounter certification and certifies the plan of care. The current standard for payment of home health services is tied to securing a written and signed certification. Certification is the act of affixing a signature, verifying the information found in a document. This same standard should be applied to face-to-face encounter certification, as intended by Congress
- Continue to pay RAPS based on verbal starts of care and condition payment of final claims on a signed certification (including face-to-face encounter) regardless of whether the encounter takes place prior to or after the start of care.
- Allow encounters by any clinic or group practice physician to be recognized as an encounter by the certifying physician

D. Encounter related to reason for home health and documentation requirements

The proposed rule at §424.22(v) spells out detailed documentation encounter requirements as follows:

- There must be documentation on the certification (separate, distinct section or addendum) that the encounter is related to the primary reason for the home health services;
- The certification must include an explanation of why the clinical finding of the encounter support that the patient is homebound and in need of covered services;
- The physician's medical record documentation must be consistent with and supportive of the documentation on the certification;

A face-to-face encounter is an event outside of the home health agency's control. An agency can facilitate a visit to the physician, but whether or not the encounter takes place is within the control of the physician and/or patient. We believe that CMS has gone beyond statutory intent in the proposed rule on two fronts: requiring that the encounter be directly for the primary reason for the prescribed home health services, and conditioning home health payment on unprecedented physician documentation in the patients medical record on the encounter including a rationalization of the certification as to how the patient meets Medicare coverage requirements.

Under the proposed encounter/certification rule, home health agencies are subject to non-payment of their claim if physicians fail to meet the unprecedented documentation requirements. In other words, the non-compliance of a party outside the control of the agency will cause financial harm to the agency and be of no consequence to the physician. Home health agencies have no way to ensure that the proposed documentation

is in the physician's record, let alone authority over the physician to guarantee that the documentation is properly composed in the first place.

Furthermore, in the absence of a uniform certification statement, the proposed physician certification would be confusing and overly burdensome to physicians. The majority of physicians would fail to provide a statement that meets CMS' proposal, which implies the need for an intricately thought out statement that connects encounter reasons to homebound status to Medicare coverage of medically necessary services. Medicare's own contractors have difficulty themselves with such a task as it is carried out in the appeals process. The current plan of care includes detailed information to support homebound status and the medical necessity of care by requiring medical diagnoses, functional status, medications, and detailed orders for care.

Home health agencies must be held harmless for any non-compliant documentation by the physician that is outside of their control. CMS should automatically apply the "without fault" provisions in section 1870 of the Social Security Act where the HHA receives a properly completed certification statement from the physician but that the physician is non-compliant with requirements for documentation in his/her record. Also, the good faith efforts of the HHA should be protected against physician non-compliance through payment guarantees under section 1879 of the Social Security Act.

Recommendations:

- Eliminate as the proposed condition of payment any requirement for physician documentation other than that a record that a timely encounter took place be maintained by the physician.
- Hold HHAs harmless regarding the veracity and validity of physician certification of face-to-face encounters. Payment should be guaranteed to HHAs up until the last day that Medicare beneficiaries are permitted to secure the face-to-face encounter. Likewise, HHAs should be entitled to payment in the event that the physician fails to complete the required certification and documentation of the encounter. This guarantee is warranted because the HHA is unable to control the actions of the physician or the patient in this regard.
- Provide Medicare payment to the HHA when an encounter did not take place, but the home health agency can demonstrate that it informed patients and physicians of encounter requirements.
- Allow home health agencies to charge patients who fail to fulfill their responsibility to have a physician encounter if payment is not made by Medicare
- Provide detailed guidance for HHABN wording when issued to patients who are ineligible because of failure to have face-to-face encounters.
- Allow home health agencies to include a template on the plan of care that the physician could complete that would include a statement about a face-to-face encounter, a space to record the date of the encounter, and a preprinted certification statement regarding related services, followed by a space for physician signature and date.

- Allow the following physician certification statement on the template: I hereby certify that I, or a non-physician practitioner, had a face-to-face encounter with the patient within 6 months prior to this certification and that I have sufficient understanding of the condition for which home health services are being provided to this patient from the patient encounter, and other sources of information, to support the orders on the plan of treatment.”
- Continue additional current plan of care and homebound and medical necessity certification statement requirements.
- Undertake an educational campaign of physicians (and approved non-physician practitioner), providing them with information about the new face-to-face requirement and the rationale for imposing this requirement. CMS should also include education about physician’s responsibility to certify that patients meet other home health benefit requirements, including homebound status (and how it is defined) and the need for skilled services. Physician education should begin immediately, through a variety of means including mail, e-mail, video, MedLearn Matters articles, etc.
- Undertake an educational campaign of beneficiaries about the new face-to-face requirement.

E. Face-to-Face Encounter by Telehealth

Section 6407 allows the use of telehealth to meet face-to-face encounter requirements. The statute refers to section 1834(m) of the Social Security Act for the telehealth services standard. The intent of Congress in including telehealth as a means to comply with face-to-face encounter requirements was to ensure access to home health services for individuals who are unable to go to a physician’s office, many of whom are bedbound or in regions of the country where access to physicians is extremely limited. The CMS proposal would require telehealth services used to meet the encounter requirement to comply with all elements of the Medicare coverage and payment standards under section 1834(m). This would include the “originating site” requirement thereby excluding the home as a place where a telehealth encounter could occur.

NAHC believes that CMS went beyond congressional intent in importing all elements of section 1834(m) into the encounter rule. The reference to 1834(m) should serve to define “telehealth” only. The coverage standards are not relevant because the encounter requirement is a home health coverage condition not a telehealth coverage condition. To do so is logically inconsistent with a requirement related to certification of eligibility for coverage of home health services. The physician certification includes the “confined to home” status of the patient. If a patient could readily get to an “originating site” outside the home, the homebound status of the patient is suspect. However, “telehealth services” as defined in 1834(m) involves equipment and services that can readily be brought into the home to accommodate the homebound (possibly bedbound) patient who must have a physician encounter to qualify for coverage of home health services.

Recommendation:

CMS should revise the proposed rule to incorporate the definition of telehealth services in section 1834(m) meaning professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary using acceptable telehealth equipment.

F. Physician and Non-physician Practitioner Employee Status

Section 6407 allows patients to meet the encounter requirement through face-to-face encounters with a nurse practitioner, clinical nurse specialist, nurse midwife or physician assistant working in collaboration with the physician. The proposed rule permits these non-physician practitioners to provide the encounter, and further requires these practitioners to document it and to communicate with the physician who writes and signs the certification.

The proposed rule limits qualified encounters by physicians who have a financial relationship with a home health agency to certify face-to-face encounters only if they meet the exceptions/exemptions to referral prohibitions found in so-called Stark rules. However, CMS also proposed that non-physician practitioners who are employees of the home health agency would be completely precluded from performing a face-to-face encounter.

Generally, a non-physician practitioner employed by a home health agency does not provide direct patient care as a non-physician practitioner, but as a registered nurse. These same individuals may also be working outside of the home health services in their practitioner role under the supervision, of or in collaboration with, a physician consistent with state law.

Non-physician practitioners should be allowed to conduct the required face-to-face encounters to the same extent that physicians are allowed to conduct the encounters. That means that if a physician is precluded because of an ownership or financial relationship with the home health agency, the non-physician practitioners should also be precluded. Likewise, if a physician with an excepted/exempted ownership or financial relationship is allowed to conduct the encounters, so should a similarly situated non-physician practitioner.

Allowing non-physician practitioners to perform the encounter under the same standards as physicians is consistent with section 6407 which authorizes no limitations such as that proposed by CMS. At the same time, it does not create any undue risk for Medicare or any improper conflict of interest. In fact, in the event that there is even a minor risk of conflict of interest, Medicare has the protection that comes from the requirement that the treating physician, not the non-physician practitioner, is the only party qualified to certify

the encounter, the homebound status, and need for home health services. The physician as gatekeeper role remains in tact.

Recommendation:

CMS should revise the proposed rule to preclude any physician or non-physician practitioner from providing the required patient encounter where there is an ownership or financial relationship that is prohibited from referring physicians under the Stark rule unless an exception or exemption is satisfied.

G. Physician Signature and Date

The proposed revisions to 42 CFR §424.22 require that the physician/non-physician practitioner sign and date the encounter certification. There is a longstanding Medicare home health policy that permits a home health agency to enter the date of receipt of a signed, but undated certification on the form as an alternative to direct physician dating. Medical review staff of the CMS contractors has also been instructed to accept any log the agency maintains as evidence of date of receipt in cases where the physician signature is not dated if the agency failed to date stamp the actual order. Instructions for completing a plan of care, and allowing notation of the date of receipt in cases where a physician fails to date a plan of care, can be found in the CMS paper-based HIM-11 manual, but have not be incorporated in the online manual system. Home health agencies report that as many as 10% of signed plans of care are not dated by physicians. To require undated plans of care to be resent to physicians for affixing a date would unnecessarily increase agency paperwork burden and cost, as well as impose delays on claim submissions without improving program integrity.

Recommendation:

CMS should continue its existing policy on acceptable alternatives to direct physician certification dating and apply such to the proposed encounter certification requirements as well. A recording of the date of receipt serves as adequate proof that the signed plan of care, and required certifications, were received by the agency prior to billing.

IV. Proposed Therapy Service Requirements

A. Summary

In the proposed HH PPS update for 2011, CMS wrote about concerns described in the notice as “current ill-defined therapy criteria.” To address these concerns, CMS proposed extensive modifications to 42 CFR 409.44 with the goal of “slowing the rate of nominal case-mix growth.” The proposed rule changes included:

- New functional assessment and reassessment requirements
- Therapy goal and clinical documentation requirements
- Timelines for visits by a “qualified therapist” on the 13th and 19th visit and every 30 days.

- Physician collaboration about therapy needs based on patient progress and restoration potential.
- Maintenance therapy coverage criteria.
- Non-coverage of therapy for conditions that are transient or reversible (e.g. post surgical debility)

NAHC generally supports the coverage and documentation requirements proposed by CMS. Specifically, NAHC supports the proposed rules for patient assessment, physician collaboration, plan of care, goal establishment, evaluation of progress toward goals through objective measures, and documentation, all of which are reflective of professional standards of practice for therapy services. The proposals align with practice guidelines established by professional therapy associations, including the American Physical Therapy Association (APTA), the Occupational Therapy Association (OTA) and the American Speech and Language Association (ASHA) and promoted by NAHC.

NAHC has concerns about, and recommends that CMS revise, the following proposals:

- Reassessment on the 13th and 19th visits
- Non-coverage of therapy services for transient and easily reversible conditions
- Limitations on coverage of maintenance therapy

B. Risk of Harm

As with the proposal for the physician face-to-face encounter, NAHC is very concerned that the proposed therapy requirements will impact Medicare beneficiaries relative to access to care and timeliness of services. With the changes set out below, it is believed that the remedy to any problem lies in internal staff/contractor education, care planning oversight, and consistent support from Medicare Administrative Contractors/Regional Home Health Intermediaries. Assuming that CMS agrees to the recommended corrections of the maintenance therapy standards and the prescriptive scheduling of assessment visits, sufficient transition time is crucial to meet the remaining requirements.

As with the physician face-to-face encounter proposal, a nationwide survey was conducted. The survey results indicate that the proposal would “have a significant effect on patient referrals, therapist care planning, patient management, and delivery of home health services. *Report* at 20-21. Specifically, the findings are as follows:

- More than 75% of respondents expect scheduling difficulties
- 53% expect difficulties in employing/contracting qualified therapists
- 20% expect that the patient assessment will be improved
- 28% expect improved care documentation
- 17% expect improved patient care

NAHC respectfully suggests that CMS take these risks into account relative to the content, timing, and the implementation support allocated to the new rule. A loss in access to restorative or maintenance therapy, even if only temporary, can cause irreparable harm to individual patients.

C. Reassessment on the 13th and 19th Visit

CMS' proposal to base continued coverage of therapy services on a functional reassessment by a qualified therapist on the 13th and 19th visit is impractical and nonproductive because it fails to address:

- Episodes that include more than one therapy discipline
- Therapy assistant oversight
- Individual patient conditions and needs

The proposal does not differentiate between qualified therapist visit timelines for single, versus multiple therapy episodes. To base patient reassessment requirements on the findings of the one therapy discipline that happens to see the patient on visits 13 or 19 would not accomplish the end of identifying the patient's condition and progress toward goals for the other therapy disciplines. Furthermore, it is not an acceptable practice for one therapy service to assess the need for other therapy services. For example, it would be out of the scope of practice for a speech language pathologist who happens to see a patient on the 13th visit in an episode to assess progress toward physical or occupational therapy goals.

In addition, this proposal fails to differentiate between therapy assistant oversight, which should be based on State practice acts, and patient status and need assessment. Most State practice acts require supervision of therapy assistants more frequently than implied by this proposal by CMS. Conduct of patient assessments on visits 13 and 19 may not coincide with the assistant supervision requirements. For example, some States require the qualified therapist to conduct every 6th visit when therapy assistant services are employed. If the CMS proposal for the 13th visit and 19th visits by a qualified therapist is instituted, the qualified therapist would be required to visit on the 6th, 12th, 13th, 18th and 19th visits.

Furthermore, the proposal establishes rigid timelines for reassessment that fail to reflect attention to individual patient's needs as required at 42 CFR §409.44(a): "A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care."

Finally, where only one therapy is provided, the 13th visit would not take place until the 5th week of service in most cases. Whereas, the 13th visit would be as early the start of the 3rd week of service if two or three different therapies are provided. Some possible negative consequences of this proposal include scheduling conflicts, unnecessary visits by the qualified therapist, and increase in the cost of delivery of home health services without added value.

Recommendations:

- Separate concerns about therapy oversight of therapy assistants from assessment/care planning, ensuring that reassessment frequency is based on individual patient needs
- Base therapy assistant oversight frequency on State practice acts
- Abandon the 13th and 19th visit proposal for reassessment
- Base reassessment timelines on individual patient needs and the duration of services as ordered in the plan of care, which is established in accord with recommendations of each professional therapist and the patient's physician
- Require an interim reassessment if there is a significant change in the patient's condition or the patient's progress deviates significantly from established goals (improvement or deterioration)
- Limit reassessment requirements to assessment of function, not a comprehensive assessment, using tools and measures deemed appropriate by professional therapy standards of practice.

As an alternative, if CMS determines that it is necessary to establish a specific timeline for reassessments, NAHC recommends that timing for reassessments be commensurate with requirements for outpatient therapy and patient need as follows:

- Each therapy service must reassess the patient at least every 30 days, and
- When there is a significant change in the patient's condition or the patient's progress deviates significantly from established goals (improvement or deterioration)

D. Non-coverage of Transient, Easily Reversible Conditions

CMS proposes the following at 42 CFR 409.44(c)(2)(iii)(A)(5): “where a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, therapy would not be considered reasonable and necessary...”

NAHC opposes the proposal to eliminate coverage of transient and easily reversible conditions. To establish these categorical exclusions assumes that recovery will take place fully and on the same timeline without use of therapy. It establishes a rule based upon the unfounded assumption that the patient's recovery does not benefit in any way from the provision of therapy. Many reversible illnesses require therapy interventions to ensure full recovery and prevent further complications or injuries.

If CMS wishes to propose a rule of this nature, it should bring forward the clinical evidence to support it. Specific listings of the disease, injury, or condition categories should be published, rather than relying on the subjective judgment of claims reviewers disabled by 20-20 hindsight. In addition, CMS should undertake such a standard of coverage through the National Coverage Determination process to ensure that it is properly evidence based.

A variety of illnesses, such as pneumonia, thrombophlebitis, and post operative conditions are easily reversible when treated with medications and rest. However, these conditions often leave patients temporarily de-conditioned and incapable of carrying out routine functional activities during the recovery period. Therapy services may be needed to teach safe transfer, promote mobility, make environmental accommodations and identify equipment needs in order to prevent falls and meet ADL needs during the recovery period.

Recommendation:

Delete the 409.44(c)(2)(iii)(A)(5). Determine coverage of skilled therapy service, even for transient conditions, in accord with 42 CFR §409.44(a): “A coverage denial is not made solely on the basis of the reviewer’s general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary’s individual need for care.”

E. Maintenance Therapy

CMS proposes the following revisions to 42 CFR §409.44:

1. When indicated, the therapist may develop a maintenance program to maintain functional status or to prevent decline in function, during the last visit(s) for rehabilitative therapy.
2. When a patient qualifies for Medicare’s home health benefit based on an intermittent skilled nursing need, a qualified therapist may develop a maintenance program to maintain functional status or to prevent decline in function, at any point in the episode.
3. Where the establishment of a maintenance program is initiated after the rehabilitative therapy program has been completed, development of a maintenance program would not be considered reasonable and necessary for the treatment of the patient’s condition.

The establishment of a maintenance therapy program along with periodic reviews of the plan has been a covered service since the start of the Medicare home health benefit. This element of Medicare covered home health services was definitively reaffirmed in the 1990 revisions to the home health coverage policies, then set out in HIM-11. Further, coverage of maintenance therapy and maintenance plan development was a significant component of the nationwide class action lawsuit settled by predecessor HCFA, Duggan v. Bowen. It is provided to beneficiaries with deteriorating or chronic conditions to ensure their safety and ability to maintain current function. According to this proposed rule, maintenance therapy may not be provided as the sole skilled service, and will be covered only if ancillary to another skilled qualifying service. If this proposal is finalized in its current form, beneficiaries would be inappropriately deprived of maintenance therapy services if, as proposed, the coverage of maintenance therapy is limited to:

1. The end of episodes of covered restorative therapy
2. During episodes otherwise when a patient qualifies for home health based on skilled nursing care needs.

In other words, an individual could not qualify for coverage of the home health benefit when the only skilled care needed is the establishment of a maintenance therapy plan and periodic reviews thereof.

Since maintenance therapy is, and should continue to be considered, a skilled and medically necessary service that requires the skills of a therapist, this restrictive coverage proposal is in conflict with Medicare law set out at 42 USC 1395f(a)(2)(C), which provides in pertinent part:

“...in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy...(emphasis added)”

The restriction that is proposed categorically denies coverage to a patient whose sole need for skilled care is the establishment of maintenance plan of treatment. Under the proposal, home health benefit eligibility is limited to those patients who also have an additional skilled care need for restorative therapy or nursing care. That additional qualification for coverage of a skilled care need is directly contrary to the statutory standards for coverage. No other skilled service requires a second skilled care need in order to qualify for the home health benefit. The proposal should be stricken as a violation of Medicare law.

This violation of the law is most apparent with the requirement that coverage of the development of a maintenance plan for the patient not previously receiving restorative therapy is limited to patients with additional skilled nursing needs. However, whether CMS believes that maintenance plan development for the restorative care patient is “reasonable and necessary” only when developed before the last restorative care visit or it is viewed a requirement for a second qualifying skilled service, the requirement is without legal or factual foundation. It is not unusual for a therapist to assess a patient on restorative care and conclude that rehabilitation is not possible without having already developed a maintenance plan of care. In fact, why would a therapist consider developing a maintenance plan until she/he concludes that restorative care is not appropriate for the patient. A follow-up visit to establish a maintenance plan is the next step but not necessarily during that same visit where restorative care was concluded.

Recommendations:

- Strike 409.44(c)(2)(iii)(B)(2) “When a patient qualifies for Medicare’s home health benefit based on an intermittent skilled nursing need, a qualified therapist may develop a maintenance program to maintain functional status or to prevent decline in function, at any point in the episode.” This requirement is in conflict with the statute which allows a beneficiary to qualify for the home health benefit based on the need for intermittent nursing, or, physical, or speech therapy or continuing occupational therapy
- Amend 409.44(c)(2)(iii)(B)(3) to coincide with the Medicare outpatient therapy policy whereby maintenance therapy is covered if development of a maintenance program is needed to maintain a patient’s functional status or to prevent decline in function because a patient’s safety is at risk. If, after an initial assessment by a therapist, it is determined that the potential for rehabilitation is insignificant, maintenance therapy is a covered service if the skills of a therapist are required for the development of the maintenance program and training the patient or caregivers.

F. Other Therapy Considerations and Recommendations

1. 409.44(c)(2)(C) states that “clinical notes written by therapy assistants may supplement the clinical record.” This should be corrected to reflect the fact that therapy assistant notes are clinical record documentation.
2. NAHC also urges CMS to address therapy coverage for conditions that may not directly impact functional status, such as pain and fall potential, which are now required OASIS reporting assessment items and process measures for home health agencies.
3. Finally, CMS should address the role of therapists in wound care, which is within a physical therapist’s scope of practice, and for which many therapists have special training and certification.

V. 36-MONTH RULE LIMITS on TRANSFERS of PROVIDER ENROLLMENT and BILLING PRIVILEGES

A. Summary

Current rules restrict the ability of a home health agency to have a change of ownership by prohibiting the transfer of the Medicare provider agreement within 36 months of the provider’s initial enrollment in Medicare, 42 CFR 424.550(b)(1). This rule took effect for ownership changes on or after January 1, 2010. However, prior to the effective date, CMS issued a Transmittal, CR 6750, on December 18, 2009 that greatly expanded the application of the rule in several ways including its application to ownership changes

within 36 months of a previous ownership change as well as minority ownership changes of 5% or more in stock, equity, or assets.

Following the issuance of the Transmittal, NAHC and others raised significant concerns about the underlying policy reasons as well as the expanded application standards. As a result of the Transmittal, access to capital and investment along with efficiency-driven industry consolidation came to a halt. Subsequently, CMS rescinded the Transmittal on May 6, 2010 while leaving the core regulation in effect. Further, CMS officials indicated that the rule would be applied utilizing a definition of “Change in Ownership” as set out in 42 CFR 489.18. The 36 month rule provision only restricted transfers of Medicare provider agreements where the home health agency ownership change occurred within 36 months of the initial enrollment of the provider in Medicare.

In June, 2010, a CMS official issued an email in response to several inquiries that set an entirely different standard for application of the 36 month rule. In fact, it restored a central feature of the rescinded Transmittal that is in conflict with the standard in the rule, 42 CR 424.550(b)(1)—the application of the restriction to ownership transfers within 36 months of an earlier ownership transfer. In addition, the official’s position expanded the application of the rule beyond ownership changes as defined in 42 CFR 489.18 to stock transfers as well. At the same time, the official’s position limited the application of the rule to 100% ownership changes.

The current proposed revisions to 42 CFR 424.550 would expand the application of the restrictions to situations where “there is a majority ownership change” (as defined at proposed 424.502) subject to a series of proposed exemptions.

NAHC opposes both the existing rule at 42 CFR 424.550(b)(1) as well as its proposed amendments. As constructed and administered to date, the existing rule does little or nothing to address the expressed rationale for the rule. In addition, the proposed changes do not fully resolve the concerns that NAHC and others have expressed throughout, continuing to jeopardize continuity of care to Medicare home health patients, access to the financial markets to facilitate proper and stable operation of a home health agency, and the ability to bring about operating efficiencies through industry consolidation. The reasons for this opposition are set forth in detail below.

Also, NAHC has serious concerns that the core rule itself exceeds the authority that CMS has regarding what it can do in the event that a home health agency changes ownership. Under 42 USC 1395bbb(c)(2)(B)(i), CMS is authorized only to conduct an expedited survey of the home health agency under new ownership within 2 months of the change in ownership. As NAHC has conveyed to CMS multiple times, the 36 month rule creates the risk that existing patients of a home health agency subject to the rule upon a change of ownership will likely be discharged immediately from that agency once the Medicare provider agreement is terminated through the requirements under the rule. That discharge will be triggered by the loss of any future payment from Medicare until the new owner receives the required survey and new Medicare provider agreement. That process would take months to complete.

Congress protected beneficiaries from this risk with section 1395bbb(c)(2)(B)(i) by supporting continuity of care and coverage under new ownership and ensuring quality of care through the expedited survey authority. In enacting this provision in 1987, Congress specifically stated that even the expedited survey was not required in all instances. The Report of the Committee on Energy and Commerce, House of Representatives that accompanied Public Law 100-203 (H.R. Rep. No. 391, 100th Congress, 1st Session 414 (1987) provides in pertinent part:

“It is the Committee’s view, too, that special circumstances may require that an individual agency be surveyed on a more than just annual basis. The Committee amendments address two such situations. The first would allow surveying organizations to conduct a standard survey within two months of any change in ownership, administration, or management. Such changes—depending upon the individuals or companies involved—may be of sufficient concern to the State or local regulators to warrant review. The amendments do not, however, mandate such a review and it is not the Committee’s intent that agencies be subject to a standard survey every time changes take place in ownership or personnel.” H.R.Rep 391 at 419.

The language of section 1395bbb(c)(2)(B)(i) and its legislative history make clear that requiring surveys upon change of ownership is not to be mandated. Further, this provision makes clear that to the extent that a survey occurs upon change of ownership, it may be done only within 2 months after the ownership transfers with the Medicare provider status. The existing 36 month rule and the proposed revisions exceed the authority provided the Secretary under section 1395bbb(c)(2)(B)(i).

Recommendations:

- Rescind the proposed revisions to 42 CFR 424.550 and the definition of “change in majority ownership” at 42 CFR 424.502
- Rescind the existing provisions at 424.550(b)(1)
- Comprehensively define and describe the program integrity or quality of care problem(s) that CMS wishes to address with improved regulatory standards
- Convene a Technical Expert Panel that includes representatives from home health agencies and the financial markets to devise appropriate requirements and/or restrictions that will address the problem(s) without disrupting continuity of patient care, access to capital, or valuable industry consolidations in a manner consistent with the Secretary’s authority.
- Issue a new proposed rule on an expedited basis.
- Apply the new rule prospectively only both to current owners of HHAs and prospective new owners.

While the process set out above is in motion, NAHC recommends that CMS utilize the authority available under 42 USC 1395bbb(c)(2)(B)(i) to conduct a standard survey of a home health agency within 2 months of any change in ownership, administration, or

management of the agency. With the survey resource allocation priorities issued by CMS, NAHC recognizes that the cost of the survey will be borne by the new owner as a result of utilizing a deemed status accrediting entity to fulfill this requirement.

In the event that CMS rejects these recommendations, NAHC recommends that CMS:

- Revise the proposed rule to clearly limit its application to ownership changes within 36 months of the provider’s initial enrollment in Medicare
- Revise the proposed rule to apply only to 100% ownership changes
- Expand the list of transaction exemptions as set out below.

B. The Problem Must Be Defined

CMS has referenced just a single concern in setting out the rationale for the existing 36 month rule as well as the proposed revisions---the existence of parties who create Medicare participating home health agencies for the sole purpose of selling the agencies as soon as possible. These operators have been labeled “flippers” and described as creating “turn-key” HHAs to sell as if they were the equivalent of retail goods at a department store.

NAHC agrees that it is important that such operators not have the opportunity to tarnish the value of home health services to Medicare beneficiaries. However, NAHC does not agree that the regulatory changes CMS has promulgated and proposed is the best way to block these operators. The approach taken by CMS has and will create more harm than good as it closes off access to the crucial financial markets, restricts consolidation opportunities, and puts patients at risk of losing continuity of care in the event of a discharge triggered by the termination of the Medicare provider agreement due to a 36 month rule-implicated transaction.

Rather than solve a problem with “turn-key “operators, the rule serves to compound and extend any of the shortcomings with such operators. For example, if an owner of an HHA is restricted from transferring ownership that owner will more likely maintain ownership for the necessary 36 months rather than abandon the operation. Such would perpetuate any noncompliance that has occurred at the hands of that owner, including quality of care deficiencies. In other words, where an owner who does not want to stay in the home health care business is blocked from selling his/her HHA, Medicare and the beneficiaries are left with an operator who is just biding time until the 36 month clock runs out.

Two other high value elements are also lost. First, lenders, investors and acquirers routinely perform extensive due diligence on the HHA before any loan, investment, or acquisition is made. This due diligence far exceeds the depth of audits, surveys, and oversight that CMS imposes on HHAs. That program protection disappears with the restraints triggered by this rule.

Second, under the rule a Medicare provider agreement subject to the 36 month restrictions is terminated when a subject ownership change is implicated. With the

termination of the Medicare agreement and the requirement that the new owner enter Medicare as an initially-enrolled provider, Medicare loses the assumption of Medicare liabilities that transfers with the assumed provider agreement.

If the perceived problem sought to be addressed by existing and proposed 36 month rules is other than “turn-key” operators and “flippers,” CMS must disclose such in order for the public to have an effective opportunity to devise comments. Notice and comment rulemaking serves a number of purposes including providing the opportunity for stakeholders and affected parties to offer their insights and expertise to help constructively develop an appropriate policy for the administrative agency. However, if the nature of the problem/issue sought to be addressed in a policy is not adequately or fully disclosed, the likelihood of constructive comments from the public is diminished or lost completely.

NAHC is prepared to work with CMS to establish standards, mechanisms, or requirements that can effectively resolve any concerns with “turn-key” or “flipper” operations. As set out below, these rules do not succeed in that regard. NAHC’s track record in devising solutions to program integrity concerns should be well evident to CMS. In the past year alone, NAHC proposed several important solutions that were enacted into law including the cap on home health outlier payments, the establishment of authority for a new provider moratorium, improved provider screening authority, and mandatory compliance plans as a condition of participation in Medicare.

C. The Solution Does Not Fit the Problem

Under the existing 42 CFR 424.550(b)(1) as well as the proposed revision, CMS requires an implicated new owner to obtain an “initial survey” to establish that the new owner is compliant with Medicare conditions of participation (CoPs). While it is crucial that home health agencies continually maintain compliance with the CoPs, here the survey requirement is set not because of any issues with the new owner, but simply because the previous owner did not have continual ownership in whole or in part for more than 36 months. In other words, the 36 month rule establishes qualifications for a new, unrelated owner of a home health agency based upon the credentials of a previous owner. That is the equivalent of imposing a penalty on an innocent bystander for the actions of an unrelated party.

Beyond the abstract inconsistency of the policy addressed herein, CMS fails to indicate what harm has been caused Medicare or Medicare beneficiaries by home health agencies that have operated for less than 36 months. To devise a solution to the conceptual problem of “turn-key” operators necessitates an understanding of the negative outcomes of such operations. Do such operators impose a higher risk of fraud, waste, and abuse? If an HHA has been operating for less than 36 months is there a higher incidence of CoP deficiencies? Are HHAs with less than 36 months of operation achieving lower than average scores in Home Health Care Compare ratings? Likewise, do new owners of HHAs that operated for less than 36 months show any of these problems at a greater incidence than other HHA new owners?

If the answers to these questions are unknown, then it is necessary to obtain the answers before attempting to devise a remedy for the perceived problem. If there are no material differences between owners with less than 36 months ownership and other owners, perhaps there is no problem to solve. If there are differences, knowing them will result in the establishment of better solutions to the problem. Similarly, if there are no outcome differences between buyers of HHAs owned by parties for less than 36 months and other new owners, there is no problem to solve. To the extent there are difference, corrective policies can be developed that target the specific nature of the concern. Failing to undertake this analysis leaves CMS with a policy based on nothing more than assumption, conjecture, and feelings.

D. Other Available Policy Tools May Provide Better Results

CMS has at its disposal authority for using other approaches to address any concerns stemming from ownership changes of HHAs. These tools include authority to impose a broad or targeted moratorium on new home health agencies. NAHC continues to support serious consideration of such a moratorium. Further, CMS can establish provider screening and credentialing standards to be applied to applicants for Medicare participation, existing providers, and new owners and managers. This authority can be used to credential parties from the beginning to better ensure that Medicare gets compliant operators and that patients receive high quality care.

One longstanding, but virtually unused authority is 42 USC 1395bbb(c)(2)(B)(i). Since 1987, Medicare has had the authority to conduct an expedited survey within 2 months of “any change in ownership, administration, or management of the agency to determine whether the change has resulted in any decline in the quality of care furnished by the agency,…” To the extent that there are concerns regarding the bona fides of the new owner’s operation of the home health agency, CMS can conduct a survey for compliance on an expedited basis, require correction of any noncompliant action, and terminate the provide from Medicare participation in the event that compliance is not achieved. If state survey resources are not available to conduct the survey, the new owner can be required to utilize, at their own expense, the services of any of the deemed status accrediting entities.

E. The Rule and Proposed Revisions Contain Internal Inconsistencies on Application to Ownership Changes Following Previous Ownership Changes

The existing 42 CFR 424.550(b)(1) establishes limitations on the transfer of the Medicare provider agreement and billing privileges enrollment in the event that there is a change in ownership within 36 months of the initial Medicare enrollment of the home health agency. The rescinded Transmittal CR 6750 improperly expanded the rule’s application to ownership changes within 36 months of a previous ownership change. Despite the rescission of that Transmittal, CMS, though its individual official, maintains that the existing rule applies to ownership changes within 36 months of a previous ownership change.

The proposed revisions to 424.550(b)(1) maintain the application standard to ownership changes “within 36 months after the effective date of the HHA’s enrollment in Medicare.” However, the proposal to define “change in majority ownership” offers the conflicting “the 36 [months] following the initial enrollment into the Medicare program or a change of ownership (including asset sale, stock transfer, merger, or consolidation).”

This internal inconsistency must be addressed. Further, CMS should rescind the policy position in this regard as issued by its official earlier this year.

NAHC believes that to the extent that the 36 month is a valid or appropriate limitation on ownership changes, it should be limited to only those ownership changes within some period after the provider’s initial enrollment. Such an approach is then targeted to those operators who simply establish a home health agency manufacturing endeavor looking for quick retail sales of their product. In that respect, the 36 month timeline is excessive given the design of selling the provider rather than operating it to provide care. A 12 month standard would be sufficient to close such businesses down..

F. To the Extent That the 36 Month Rule is Retained It Should Only Apply to 100% Direct Ownership Changes

The proposed revisions to 42 CFR 424.550(b)(1) modify the application of the rule to apply to “a change in majority ownership of a home health agency by sale (including asset sales, stock transfers, mergers, consolidations)..” Current application of the 36 month rule restrictions is to changes in ownership as defined under 42 CFR 489.18 and (according to the CMS official’s email) 100% ownership changes of stock or assets.

It is not reasonable to assume that a change in majority ownership results in any significant change in the day to day operation of a home health agency. Other factors may demonstrate that a majority ownership change warrants a survey to determine continued compliance with Medicare CoPs. These would include management changes, service area changes, office relocation, and changes in the service disciplines provided. If there is a majority ownership change accompanied by other elements that may raise questions about continued compliance, CMS has the discretion to conduct a standard survey and in-depth compliance audit. Such decisions should be made on a case-by-case basis rather than instituting an across the board block to continued Medicare participation that ends to wholesale patient discharge.

Similarly, the rule should apply only to direct ownership changes. In home health care, as in other businesses, the direct provider of services may be owned by an entity that owns another entity that owns the home health agency. An ownership change of the parent corporation is unlikely to result in any change in the day to day operations affecting the quality of patient services or compliance performance of the home health agency. In the event that there are changes that occur at the home health agency level, CMS could conduct a targeted survey. With the responsibility to report any management changes, the

home health agency provides all the needed information for CMS to assess the need for the focused survey.

G. Exceptions Should Be Modified to Include Low-Risk Transactions

The proposed rule includes four exceptions that attempt to address concerns voiced by NAHC and others that an overbroad application of the 36 month rule hinders normal operations of bona fide businesses that pose little or no risk to Medicare and Medicare beneficiaries. NAHC recommends that these exceptions be modified to include the numerous other transactions that do not rise to a level of risk justifying either a prohibition on the transfer of the provider agreement and billing privileges or necessitating an initial survey following the termination of the agreement held by the previous owner.

Exceptions:

1. Publicly-traded company acquires an HHA when both have submitted cost reports for the previous 5 years

NAHC recommends an exception for any “experienced” acquiring party whether a private or public company. The additional legal and oversight requirements applicable to public companies do not make a difference with respect to compliance with Medicare CoPs and other Medicare laws to warrant an exclusive exception. The performance measure is Medicare performance and all experienced entities can be measured alike regardless of tax status, shareholder makeup, or corporate structure. Any experienced company that owns a Medicare provider should be allowed to assume the Medicare agreement of any home health agency subject to Medicare exercising its authority to do a post-acquisition survey.

NAHC submits that a 5-year cost reporting experience is unnecessarily strict as an experienced provider is subject to standard surveys at least every 36 months and more often annually.

NAHC further recommends that a home health agency can be acquired by other parties without application of the 36 month rule where the HHA is “experienced” and there are no indications of changes in the day-to-day operations of the HHA triggered by the ownership change sufficient to warrant a survey.

“Experienced” should be defined as having at least one survey within the previous 36 months.

2. Corporate restructuring in the HHA parent company

The proposed exception is limited to corporate restructurings where the HHA submitted a cost report for the previous 5 years. NAHC recommends that here be

no qualifiers on allowing corporate restructurings where the chain of ownership ultimately remains the same as prior to the restructuring. The experience of the HHA has no bearing on whether that restructuring changes day-to-day operations. Restructurings of any nature are highly unlikely to change the way home health services are provided at all, or to a degree sufficient to warrant termination of the provider agreement, wholesale patient discharge, and suspension of all services until Medicare participation is re-established.

For example, changing from one corporate structure to another such as an LLC to a subsidiary corporation does not lead to any operational change that would necessitate a survey, let alone the consequences brought on by the 36 month rule. Similarly, moving one subsidiary under another wholly-owned corporation to another wholly-owned corporation does not affect services to the extent justifying anything other than a report of the change.

3. Change in existing business structure

This exception should apply provided there is no change in the individual owners regardless as to whether there is a change in majority ownership.

4. Death of an owner who owns 49 percent or less

This exception is inconsequential because there would be no change in majority ownership. The exception should be revised to include the death of an owner or partner provided that the remaining owners or partners retain their ownership.

5. Additional Exceptions

NAHC proposes the following additional exceptions:

- Ownership changes as a result of bankruptcy with court approval

This exception is needed to re-establish access to loans and lines of credit. Lenders will not provide loans today without collateral. That collateral for any business usually includes the business itself. If an HHA can be devalued to zero because of a potential application of the 36 month rule in the event of a bankruptcy, no loans will be available. Currently, the rule creates that barrier to access to credit.

Typically, a bankruptcy will bring about at least two ownership transfers; one from the existing owner to the Trustee in Bankruptcy and a second from the Trustee to a buyer as the Trustee liquidates assets to satisfy creditors. The liquidation may transfer ownership to the lender depending on the nature of the collateral arrangement. While the risk of bankruptcy is extremely low, the abstract risk itself discourages lenders from extending credit.

- Foreclosure on collateral by a lender outside of bankruptcy

This exception serves the same purpose as the bankruptcy exception proposal

- Acquisition of an HHA within X months of initial Medicare enrollment where the HHA to be acquired is considered to be a bona fide operating entity rather than a “turn-key” enterprise as demonstrated by a complaint survey subsequent to initial enrollment and a patient census that exceeds 5% of the active patient census in the geographic service area of the HHA

CMS has expressed concerns regarding a business model that is intended simply to flip ownership of Medicare HHAs in contrast to those that are formed for the primary purpose of providing home health services. The two different business models can be distinguished based on the size of its patient population. NAHC suggest a 5% of market standard as it reflects that a more than token patient population demonstrates the primary purpose in the establishment of the HHA. Also, the patient census size indicates the level of patient difficulties that would occur if the provider agreement was terminated due to the rule.

- Estate planning changes, i.e. the HHA stays in the family

Transition to a family owned business may be the best ownership transfer for Medicare and Medicare patients. It shows a strong commitment to the delivery of care as the central purpose of the business.

- Indirect ownership changes without significant day-to-day management change

For the reasons set forth above, if CMS does not change the rule consistent with NAHC recommendations, CMS should exempt indirect ownership changes where there is limited managerial change regarding the direct provision of care should be excepted. The key concern is whether patients can expect continuity of the same (or better) quality of care under new, indirect ownership. That is determined at the HHA level not the parent company boardroom.

H. The Rule Should Apply Prospectively Only

To the extent that CMS continues any form of the current 36 month rule, NAHC recommends that the existing rule and any revisions be applied prospectively only. Specifically, no HHA that is currently Medicare enrolled should be subject to the rule in the event of any implicated ownership change as they entered into Medicare without a restriction on the sale of the HHA other than those restrictions existing at that time. At most, CMS should apply the rule to HHAs initially enrolled in Medicare on January 1, 2010 or later, the effective date of the original 36 month rule. Otherwise, the application of the rule to pre-existing HHAs alienates the value and financial stability of the business in ways that will affect existing creditors, investors, and owners.

I. Conclusion

NAHC believes that the 36 month rule is well-founded in its purpose and intent. However, the rule is not appropriate to the problem it seeks to address as it will negatively impact on bona fide home health agencies and the patients they serve. The rule should be redesigned wholesale or significantly revised to better balance the interests of patients, providers, and Medicare. NAHC is ready, willing, and able to work with CMS to achieve the program integrity protection purpose behind this rule.

VI. HH CAHPS

A. Summary

Home health agencies that serve 60 or more eligible patients in a calendar year will be required to contract with a CMS approved Home Health Consumer Assessment of Healthcare Providers and Services (HHCAPHS) vendor to conduct patient surveys.

The timelines established in the PPS rule require:

- Submission of dry run data from at least one month in the third quarter of 2010 (submitted by 1/21/11);
- Full participation by submission of required data from the fourth quarter of 2010 onward; and
- Agencies with fewer than 60 eligible patients must apply for an exemption.

Agencies that do not qualify for an exemption that do not submit data in accord with the specified timelines will be subject to a two percent reduction in the market basket updates beginning in 2012.

Specifically, in order to qualify for a full market basket update in 2012, HHCAPHS dry run data from at least one month in the third quarter of 2010 (July through September) and HHCAPHS survey data from the fourth quarter of 2010 (October through December) and the first quarter of 2011 (January through March) must be submitted to the HHCAPHS Data Center by the agency's approved vendor. Beginning in 2013 full market basket update will be based on CAHPS data submission for a full year.

B. Risk of Harm

The PPS 2011 final rule will not be published until late October or November. Although CMS included information about its plans for HH CAHPS in previous *Federal Register* notices, the 2011 HH PPS notice is the first in which HH CAHPS is officially proposed as a regulatory requirement. As of the end of July 2010, only 2,109 of the more than 10,500 Medicare certified home health agencies had selected a CAHPS vendor. In addition, only 1,114 eligible agencies applied for a CAHPS exemption, leaving more than 7,200 agencies that had not completed necessary steps related to CAHPS. This poor rate

of participation is indicative of the need to educate home health agencies about these new requirements and provide a reasonable opportunity for implementation within the agencies before imposing any penalty for noncompliance.

HH CAHPS is a significant operational change for home health agencies. Also, it is in the interest of CMS and Medicare beneficiaries that CAHPS be administered appropriately by home health agencies. The early experiences with OASIS demonstrate that such a major change be managed carefully and patiently by CMS. A full twelve months of data collection is the best way for proper implementation.

The cost of conducting HH CAHPS surveys is not reflected in Medicare payments or in market basket updates. Agencies responding to a poll conducted by NAHC reported projected annual vendor costs for HH CAHPS ranging from \$3500 for small agencies (300-500 patients annually) to \$85,000 by one of the nation's largest agencies. These numbers do not reflect the agencies' administrative costs. These new costs are being imposed at a time that home health agencies are facing drastic cuts in reimbursement.

Recommendations:

- Finalize the regulation at 484.250 requiring home health agencies to contract with an approved HH CAHPS vendor and submit HH CAHPS data effective January 1, 2011, but delay imposition of financial the penalties (market basket minus two percent) until 2013 based on 2012 CAHPS compliance
- Undertake additional educational efforts directly via additional Medlearn Matters articles as well as through outreach by state survey agencies, RHHIs and MACs
- Reimburse the full costs that agencies incur for HH CAHPS activities, including related administrative costs and vendor fees and administrative costs

VII. WAGE INDEX

NAHC has long voiced its opposition to the wage index in use by CMS with HH PPS. That wage index completely fails to accurately address geographic differences in wages. While NAHC realizes that a home care specific wage index is not feasible, CMS must realize the severe shortcomings of the present wage index applied to home health services. First, it uses a hospital wage index that is wholly different than the one applied to area hospitals. In failing to apply the same standards to home health services as are applied to inpatient hospital services, hospitals are given an unfair market advantage in the recruitment and retention of staff. Hospitals and home health agencies often compete for the same nurses, therapists, and personal care aides. However, with the hospital wage index operating with the numerous types of geographic reclassifications and the rural floor on the index, each year the resulting index for home health agencies is far different than the index applied to the hospitals servicing the same patient population.

NAHC has made recommendations to CMS on numerous occasions as to how a reclassification approach, using the hospital reclassifications, could effectively address this concern.

Second, the annual wage index is subject to swings in area values that are far beyond manageable by the providers. With a wage index reduction of 10 to 14 points in some rates, it is impossible to sensibly budget a fiscal year, particularly when the index is not published until a few months before a calendar year. NAHC continues to recommend that CMS apply limits on the decreases and increases that can occur from one year to the next with the wage index.

Overall, NAHC supports the wholesale replacement of the wage index in line with the recommendations of the Medicare Payment Advisory Commission. The Affordable Care Act of 2010 gives CMS all the authority needed to promulgate the appropriate changes. However, NAHC does not support the institution of a new index model except when it applies in all provider sectors with whatever distinctions are appropriate to a provider's employment mix.

VIII. NEW PROVIDER CAPITALIZATION

CMS proposes a number of changes with respect to the requirements for 3 months capitalization for newly participating and enrolled home health agencies. NAHC shares CMS's desire to establish standards to ensure that applicant providers meet rigid criteria that are intended to ensure that only high qualified, well-intentioned organizations gain the privilege of Medicare participation as a home health agency.

The capitalization requirements have been applied over the years to make sure that only financially stable organizations qualify. However, in recent months, it appears that the application of the capitalization standards changed with the level of capitalization changing throughout the provider approval process.

The proposed capitalization rule changes would put the evolved policy practices into a formal rule. In doing so, applicants would likely need to present proof of 3 months capitalizations several times during the approval process with the level of capitalization changing throughout. While NAHC agrees that it is important that a new provider be financially stable at the start date of Medicare participation and for 3 months thereafter, we recommend that the capitalization rule operate with certain structural elements:

Recommendations:

- There must be transparency throughout the process. An applicant must be able to readily determine the level of capitalization at every stage of the review process and be aware of its responsibilities in that regard before Medicare or its contractor's reviews compliance. In other words, the applicant must be able to determine how much capitalization is needed at the time of application through the last stage of the review process
- Notice must be given to the applicant whenever the capitalization amount changes with sufficient time for the applicant to attempt to secure any capitalization shortfall and to provide the capitalization status to Medicare

- The capitalization standards must be evidenced-based and reviewable by an objective and independent person or entity

Further, NAHC recommends that CMS consider additional safeguards in provider certification including implementing the provider screening and new provider moratoria authority contained in the Affordable Care Act of 2010. NAHC is very interested in working with CMS to get quick implantation of this authority.

IX. MISCELLANEOUS TOPICS

- Hypertension Diagnosis Coding Under the HHPPS
- Collecting Additional Claims Data for Future Home Health Prospective Payment System (HHPPS)
- Future Plans To Group HHPPS Claims Centrally During Claims Processing

A. Hypertension Diagnosis Coding Under the HHPPS

CMS identified a significant change in the assignment of hypertension codes 401.1 (benign hypertension) and 401.9 (unspecified hypertension) to home health patients. According to the proposed rule, CMS asserts that this is due, in part, to revised classification of blood pressure by the National Heart Association in 2003 and, as a nominal change, these codes should be eliminated from home health case mix. Although CMS believes that inclusion of these two hypertension codes reduces the case-mix model accuracy, they did not test for their impact. Further, CMS did not conduct an analysis of the impact of elimination of these two codes on resource utilization and payment to home health agencies.

CMS surmises, but does not provide supporting evidence, that four years after recommended changes in classification of conditions, physicians finally adopted the National Heart Associations recommendations. According to clinical resources, benign hypertension is assigned as a diagnosis when patients do not exhibit classic symptoms of hypertension. Essential hypertension is assigned when the underlying cause of hypertension cannot be established. However, both benign and essential hypertension require treatment, because if they remain untreated, the result will be damage to bodily systems. NAHC has included an analysis of the impact of hypertension codes in its case-mix studies that are currently underway. The final reports from these studies will be included as appendices to our official comments

In an analysis of 1.1 million episodes conducted by OCS HomeCare, Inc., the effect of elimination of diagnosis codes 401.1 and 401.9 on all hypertension episodes was an average of \$131 per episode. The overall effect of this proposed action on the 1.1 million episodes analyzed by OCS for that period would produce a -1.87 percent in payment. Elimination of the diagnoses codes would reduce the reliability of the case mix model, since in the current model it was demonstrated to have an impact on resource utilization, thereby reducing the reliability of the case-mix model. Further, elimination of these codes from the model would constitute double dipping by CMS when carried out

simultaneously with the case mix creep adjustment, which reflects creep due to the increase in hypertension coding.

Recommendations:

It is not reasonable to eliminate case mix variables, which were established based on extensive research, without conducting a thorough investigation of the impact on resource utilization. Retain the hypertension diagnosis codes until further research is conducted on physician practice related to assignment and treatment of patients with these diagnoses. Should it be determined that these codes do not impact resource utilization to a significant extent, reallocate case-mix points currently assigned to these diagnoses within the system, or establish budget neutrality.

B. Collecting Additional Claims Data for Future HHPPS

The HHPPS notice establishes a plan for collection of new Healthcare Common Procedure Coding System (HCPCS) "G" codes and the reporting of these new codes on home health claims beginning in 2011. Current G codes for nursing and therapy services that are recorded on home health claims at form locator 44 are: G051-PT, G052-OT, G053-SLP, and G054-SN. Although not part of rulemaking, CMS used this HHPPS Update notice as a vehicle for advising home health agencies of the changes that it intends to put in place. CMS plans to request new therapy G codes to collect information that could be used to evaluate the extent of shift in the provision of therapy visits by therapy assistants, rather than qualified therapists. In addition, CMS plans to require reporting of yet another new G code when a qualified therapy is for the purpose of maintenance therapy.

CMS also plans to require home health agencies to report specific G codes for skilled nursing services. G054 would indicate "direct skilled nursing care to the patient by a licensed nurse." Two new codes would be established for reporting other covered nursing services. A single G code has been proposed for reporting both Management and Evaluation of an unskilled plan of care and Observation & Assessment of a patient's unstable clinical condition. These services require different nursing skills, and are provided based on very differing patient needs. Finally, a new nursing G code would be established for reporting training and education of patients or family members.

Recommendations:

1. Carefully consider that new coding requirements always carry with them the burden of system changes and education of providers
2. Delay implementation until 2012 to allow:
 - Vendors sufficient time to carry out necessary programming changes (minimum three months from establishment of HCPCS codes and guidance); and

- Development and dissemination of educational materials for providers on how to determine which code(s) to report, particularly when multiple services are provided during a visit, which is often the case
3. Carefully analyze programming burdens before requiring reporting of more than one code per line
 4. Establish two separate codes for Management & Evaluation and Observation & Assessment. These are inherently different service based on different patient needs and different nursing skills
 5. Continue to make coverage determinations based on medical review of clinical records, and do not resort to decisions based on such considerations as frequency of the appearance of certain codes on home health claims
 6. Do not use information collected until the accuracy of the information collected has been validated

C. Solicitation of Comments: Future Plans to Group HHPPS Claims Centrally During Claims Processing

CMS has solicited public comments on an idea for future changes to claims submission and processing procedures whereby HIPPS codes would no longer be assigned by home health agencies as they now are, but would be assigned by CMS during claim processing. This change would create a requirement to report all OASIS items necessary to group an episode on the HHPPS bill.

NAHC has several concerns about this proposed change:

- The proposal fails to identify how such a change will affect current RAP and final claim processing timelines
- It fails to identify how and when the grouper assignment would be communicated back to agencies on RAPS and claims
- Access to timely information about accounts receivable is essential to the conduct of business since agencies must be able to project revenue in real time
- Although the notice refers to HIPPS errors on the part of home health agencies and vendors, there is no reference to errors that have been identified in CMS calculators by agencies and vendors over the years. Findings by the industry have been effectively used by CMS contractors to make corrections and prevent costly payment errors
- CMS identifies Health Insurance Prospective Payment System (HIPPS) code calculation during claims processing as a reduction in burden for home health agencies. However, vendors will continue to create calculators for their customers to ensure that the CMS HIPPS codes assignment and payment calculations are correct
- Agencies will have a new burden of reporting all OASIS case-mix items on claims. The proposed change doesn't eliminate the need to ensure that the OASIS items that are generated at the agency level are accurate.

- One burden, calculation of the Home Health Resource Group, will be replaced by another burden, the translation of the OASIS items into a string that must be reported on the claim

Recommendations:

CMS should not change the current process for HIPPS code assignment by home health agencies. Rather, CMS should require vendors and agencies to submit HIPPS codes that have been validated against a CMS calculator which has been fully tested.

If CMS decides to implement its proposal, timeliness of claims processing should not be affected and accounts receivable information should be made available in a timely manner. The industry should be permitted to actively participate in testing any HIPPS calculator before it is used. The CMS HIPPS code calculator should be made available to home health agencies and vendors to give them the option to use them to project accounts receivable, rather than requiring them to wait for reports from CMS contractors responsible for assigning HIPPS codes. Finally, this new system would require assurances of 100 percent accuracy in linkage of OASIS case mix items to claims in order to be an improvement on the current system

IX. HOSPICE FACE-TO-FACE ENCOUNTER

A. Summary

In a June 17 letter, Hospice Association of America (HAA), a NAHC affiliate provided an initial set of recommendations to CMS on the hospice face-to-face requirement. A copy of it is appended for your reference. (Attached as Exhibit C). Since that time we have had the opportunity to review the proposed regulatory changes and analyze their impact on hospice operations. While we are supportive of the goals and motivations that led Congress to enact the new hospice requirement, we are increasingly concerned that the new requirement will create significant challenges for hospice programs of all sizes nationwide, and particularly for small hospice programs in rural areas. These challenges are of sufficient magnitude that they will demand deliberate planning by hospices to ensure they budget their financial, clinical, and operational resources to comply with the new requirement. For these reasons and those provided below, we urge that CMS delay the effective date for the face-to-face requirement to no earlier than Jan. 1, 2012, or until such time as the Secretary of Health and Human Services and hospice organizations are able to fully address the added responsibilities and operational concerns related to this requirement, and ascertain departmental and hospice provider readiness.

B. Insufficient Hospice Physician/NP Staffing to Meet the Requirement

Under current practice, many hospice programs work with the patient's primary care physician and do not assume direct medical care of their patients, thus they do not schedule physician or NP home visits on a regular basis. Instead, continuing eligibility is determined through hospice physician examination of a wide range of clinical findings

reported by members of the inter-disciplinary team. A number of hospice programs have expressed apprehension that they will be unable to meet the face-to-face requirement due to insufficient hospice physician/NP availability, limited resources and/or practitioner shortage in the geographic area. Where sufficient clinical resources are available, hospices may need to contract with or hire additional clinicians. If this is the case, this will add a significant administrative and financial burden on hospice programs.

Recommendation:

In addition to the delay, once readiness has been established by the Secretary, we recommend phasing in the requirement for a face-to-face encounter by applying it first to hospice programs with a high proportion of long-stay patients. CMS should allow the face-to-face requirement to be fulfilled by the patient's attending physician as well as by a hospice physician/NP. CMS should also give special consideration to the additional burden that this requirement will place on rural and underserved areas, and exempt from the requirement geographical areas that are designated Health Professional Shortage Areas.

C. Prohibitive Costs of the Hospice Face-to-face Encounter Requirement

As mentioned in our first issue (above), most hospice programs do not currently schedule regular face-to-face encounters between a hospice physician/NP and the patient. Home visits by hospice physicians/NPs can be very costly, particularly for hospices that cover a large geographical area. Hospices that are currently working to incorporate the requirement into their operations report that costs have expanded exponentially as a result.

Recommendation:

We urge that CMS ensure that the hospice physician/NP face-to-face encounter is billable to Medicare by the hospice program or by the attending physician in cases where he makes the visit. CMS should specify the billing code under which either the hospice program or attending physician must bill for the encounter; this code should include reimbursement of mileage and travel time for a high-level practitioner. In addition, as current payment rates do not reflect the added administrative costs for implementing the face-to-face requirement, CMS should increase hospice rates of payment to reflect the additional cost burdens.

D. Inadequate CMS Resources to Ensure Accuracy of Previous Hospice Service.

The resource currently available for use by hospices (primarily the Common Working File – CWF) in determining previous history of hospice care by a patient are not sufficiently up to date to be able to rely on them with absolute accuracy for purposes of establishing the patient's full history of hospice care and current benefit period. Nor can hospices fully rely on reports by patients or family members to document previous hospice service. CMS is contemplating incorporation of hospice data into the redesigned

Provider Statistical and Reimbursement Report (PS&R); however, it is unclear when the PS&R might be able to provide better information so that hospices can track previous patient service by another hospice with certainty.

Recommendation:

Until such time as CMS can ensure that the CWF and/or PS&R hospice data are accurate and timely, a hospice should be responsible for counting only those benefit periods during which the patient was under its care. Alternatively, CMS should provide clear guidance on what would constitute a hospice’s “best effort” to secure the patient’s full hospice history for establishing the proper benefit period, and provide a “hold harmless” for those programs who have met the “best effort” standard.

E. Challenges Related to Meeting Face-to-face Requirement for Patients Readmitted While Actively Dying

It is not unusual for a patient who has previously been served by a hospice and revoked election to be readmitted to hospice in the latest stage of his or her terminal diagnosis. Some patients resume care for only a day or two before they die. In cases where resumption of care begins very close to the 180-day benefit period or subsequent benefit periods, a hospice may not be able to provide needed care on a timely basis while at the same time ensuring that a physician/NP encounter takes place prior to the patient crossing benefit periods. If the patient has been on service by a different hospice previously and accurate information related to the patient’s care history may not be available through the CWF, difficulties in meeting the face-to-face encounter requirement will be exacerbated.

Recommendation:

CMS should forgo imposition of the face-to-face requirement in cases where a patient’s referring physician and/or hospice staff assess a patient as imminently terminal and must begin treatment immediately to ensure that the patient receives needed services.

F. Application of Benefit Period Standard for Patients with Sequential Hospice Care/Terminal Diagnoses

Hospices have also raised an additional concern with respect to counting hospice care for purposes of the benefit period in that there are cases where a patient may have been diagnosed as terminally ill, elected the hospice benefit, and subsequently underwent recovery and left hospice care. There are instances in which these patients return to hospice care at a later date (sometimes years later) and in some cases with a different terminal condition. However, the hospice benefit periods are calculated on full hospice care history rather than based on the terminal diagnosis that justifies care currently being provided.

Recommendation:

CMS should apply the benefit period calculation requirement to the current terminal diagnosis, as opposed to all service under hospice throughout the patient’s care history. Additionally, in cases where a patient has revoked his or her hospice election or has been discharged from hospice services for whatever reason and is off hospice service for a significant period of time, CMS should allow hospice programs to “start the clock” over again for purposes of establishing when the face-to-face requirement must be met.

G. Potential for Professional/Ethical Conflict

Under current Medicare law, patients electing hospice maintain eligibility to receive services under the regular Medicare benefit for health concerns not related to the terminal diagnosis. Hospice programs have raised concerns that hospice physicians/NPs may, during their visits to gather clinical findings to meet the face-to-face encounter requirement, be expected by the patient or family members to treat the patient for issues that are not related to the terminal diagnosis. This is a particular concern in cases where the patient is not under the direct medical care of the hospice medical director but under the care of his or her primary care physician.

Recommendation:

CMS should acknowledge the potential for such professional/ethical conflicts and make every effort to avoid establishment of any barriers (either through the hospice conditions of participation or coverage requirements) that would prevent the physician or NP from providing adequate notice or explanation to a patient or responsible family member regarding the purpose of the face-to-face encounter.

X. CONCLUSION

Thank you for the opportunity to submit these comments in response to the Notice of Proposed Rulemaking. We offer them in a sincere and constructive fashion with the hope that CMS will accept our recommendations in developing the Final Rule.

Very truly yours,

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